October 10, 2019

Via Electronic Mail Only
PainandSUDTreatment@cms.hhs.gov
Centers for Medicare & Medicaid Services
Department of Health and Services

Re: Request for Information for the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment

Dear Administrator Verma:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide you with information regarding the CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment. AdvaMed and its members are committed to working with CMS and other stakeholders to broaden the dialogue as it relates to the use of devices to combat the opioid epidemic that is confronting our nation and its citizens. We are encouraged by the engagement of CMS and others in these issues.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests to treat and manage pain.

AdvaMed has previously engaged CMS on this issue and strongly believes in the capability of devices that treat chronic and acute pain to reduce the prescription and use of opioids. We also encourage CMS and others to consider the adoption of policies that allow providers and patients to access and use digital and other remote technologies to treat their Substance Use Disorders (SUD).

Given the link between opioid abuse and chronic and acute pain, we believe CMS can and should actively support methods to alleviate pain without opioids by implementing appropriate coverage, coding, and reimbursement policies. Non-opioid interventions may include minimally invasive surgery, and other invasive and non-invasive pain management modalities, such as spinal cord stimulators, implantable intraspinal drug infusion pumps, cooled and standard radiofrequency neuroablation, electromagnetic

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energy, digital therapeutics, vertebral augmentation, ultrasound guided regional anesthesia, and portable continuous pain relief systems—including elastomeric pumps.

The CMS request for information poses a series of questions regarding acute and chronic pain and SUD. AdvaMed would like to address several of these questions on behalf of our members.

- **What actions can CMS take to enhance access to appropriate care for acute and/or chronic pain in Medicare and Medicaid?** What actions could CMS take to improve access to evidence-based, FDA-approved MAT or other therapies in Medicare and Medicaid?

AdvaMed member companies manufacture a range of technologies that can markedly reduce the need to prescribe opioids to patients experiencing chronic and acute pain. One of the issues our members experience, related to the deployment of opioid alternative devices, is the inability of patients to access these innovations at the appropriate time. These access concerns are the result of various issues including delays in acquiring an appropriate code (e.g. CPT or HCPCS) to identify and track use of the device. Additionally, coverage delays in the form of requirements such as prior authorization or “step therapy”, which may require patients to undergo drug therapy for pain relief (posing possible addiction risk) prior to being able to utilize a device-based intervention, are impeding patient access to needed technologies.

To avoid and manage SUD and the prescription and use of opioids, it is critically important that patients can access alternatives at a time that suits their individual needs—which can vary depending upon family and personal history or other physical and psychological conditions. AdvaMed would encourage CMS to consider recommendations regarding code review and approval processes that recognize the necessity of bringing evidence-based opioid alternative devices to the patients that need them with minimal delay—including new devices and iterative improvements to existing devices. AdvaMed also recommends that coverage policies be modified to accommodate patients who may be at high-risk of SUD due to personal or family history. CMS should provide coverage, payment, and immediate access to device-based treatments that avoid the prescription and use of opioids at the onset of treatment instead of requiring these patients to undergo a step-wise treatment approach that may start with drug therapy.

- **What, if any, payment and coverage policies under Medicare and/or Medicaid for the treatment of acute and/or chronic pain, do you believe may have contributed to the use of opioids?** What, if any, payment and coverage policies in Medicare and/or Medicaid have enhanced or impeded access to non-opioid treatment of acute and/or chronic pain? What, if any, payment and coverage policies in Medicare and/or Medicaid have enhanced...
or impeded the identification of, and access to treatment by, beneficiaries with SUDs including OUD?

There are a variety of device-based alternatives available to manage acute pain with limited or no opioids (thereby limiting or avoiding the risks of developing SUD). However, disincentives in the Medicare payment system may limit and/or prevent access to these technologies. The existing payment systems do not include a mechanism for separate payment of non-opioid device-based alternatives when included as part of inpatient, outpatient, or post-acute procedures. Specifically, some devices and services used to avoid opioids for acute, post-surgical, pain are currently bundled into the supply or equipment costs for the overall procedure. Consequently, hospitals may have financial disincentives to prescribe/use the device in lieu of prescribing a lower cost and potentially addictive opioid that will be reimbursed under Part D - even in a patient that may be at high-risk for SUD. CMS should modify the hospital and post-acute payment systems to resolve this disparity in patient access to these alternative devices by creating a mechanism for separate payment for device-based opioid alternative supplies, equipment, and guidance procedures that are utilized in hospital, emergency, and other settings for urgent and acute pain management. Any such modification should also allow providers who choose to deploy these technologies in the treatment of their acute and/or chronic pain patients, especially those at high-risk for developing SUD, to do so without being penalized. In turn, manufacturers of those devices should continue to track and produce evidence-based information supporting the role of their technologies in reducing the prescription and use of potentially addictive opioids.

There are also many devices used to treat patients who experience chronic pain. As CMS evaluates the OPPS payment system, per the directives of Sections 6032 and 6082 of the SUPPORT Act, we would ask the agency to consider means to ensure that evidence-based non-opioid alternative devices for pain management are not overlooked due to reimbursement concerns. AdvaMed would ask CMS to consider payment system changes that will encourage providers to use these devices when needed without fear of negative financial impacts. We would also suggest that CMS consider other outpatient payment policy changes that will improve utilization of these devices, when needed, such as pass-through, or other add-on payments, and new technology APC assignments. In the case of pass-through designation and new technology APCs, AdvaMed also recommends that CMS modify the qualifying criteria to also include consideration of the ability to avoid use of opioids as a substantial clinical improvement and to reduce the time for processing and approving the designation for these types of technologies.

Any payment policy changes should minimize financial burdens to use needed devices by not increasing patient liability. For example, add-on payments and other mechanisms that will appropriately adjust reimbursement for device alternatives to opioids should not
increase patient cost. CMS should also consider implementing policy changes that will create co-pay parity between opioids and device-based alternatives to allow patients and their physicians to choose the best treatment, as opposed to the least expensive, based upon individual need.

The discrepancy between ASC and OPPS beneficiary cost-sharing amounts can also be a barrier to patient access to non-opioid pain management alternatives in the ASC setting, and may lead to lack of care, delay in care, or migration of care from the ASC to other settings. Specifically, the lack of a deductible cap on the ASC coinsurance amount may result in higher patient cost-sharing for certain device-intensive non-opioid pain management alternatives in the ASC setting. While we recognize that the law establishes coinsurance at 20 percent of Medicare’s allowance, AdvaMed recommends that CMS work with Congress to remove this barrier to non-opioid pain management alternatives in the ASC setting.

- What evidence-based treatments, Food and Drug Administration (FDA)- approved evidence-based medical devices, applications, and/or services and items for the following conditions are not covered, or have limited coverage for Medicare beneficiaries with:
  a. Acute and/or chronic pain
  b. Pain and behavioral health needs requiring integrated care across pain management and substance use disorder (SUDs), with consideration of high-risk patients (i.e. multiple medications, suicide risk)?
  What actions could CMS take to improve access to evidence-based, FDA-approved MAT or other therapies in Medicare and Medicaid, including for special populations (for example individuals living in health professional shortage areas)?
  What can CMS do to expand program access to the treatment of SUDs, including OUD, in Medicare and Medicaid through remote patient monitoring, telehealth, telecommunications and other technologies?

In some instances, patients are required to undergo additional medical evaluation or treatment prior to receiving device-based non-opioid interventions for chronic pain. The additional requirements pose barriers to access and treatment delays for beneficiaries, especially those in areas with limited or no qualified providers to conduct the evaluation, prolonging their exposure to opioids and increasing their risks of addiction. Allowing these evaluations to be conducted via telehealth could assist in minimaxing the risks associated with opioid use.

While there is a lot of activity in the area of developing technologies that can be used to treat and manage SUD, the payment systems pose problems regarding access to, and payment for, non-systemic based opioid alternatives that can be used to manage SUD. In

AdvaMed members are using and developing app-based and other forms of digital and telehealth technology that may allow patients to be self or remotely managed for their SUD. These app-based options present effective alternatives to the use of drug-based treatment of SUD. While the utility of these devices is promising, the current Medicare payment systems do not include a benefit category that will allow providers to receive reimbursement for these times of treatment alternatives. In managing acute and chronic pain, we encourage CMS to examine and address the impact of benefits category constraints on access to SUD treatment interventions.

Effective monitoring is also critical in the management and treatment of SUD. Diagnostic testing creates a viable method for monitoring patients for the presence of a variety of opioids. CMS should ensure that access to appropriate testing is consistent with relevant guidelines and is not negatively impacted by overly restrictive coverage or payment policies.

- **How can Medicare and Medicaid data collection for acute and chronic pain better support coverage, payment, treatment, access policies, and ongoing monitoring?**; **What other issues should CMS consider to improve coverage and payment policies in Medicare and Medicaid to enhance access to and effective management of beneficiaries with acute and/or chronic pain?**

The pain management issues that are the root cause of many opioid dependency issues are prevalent in Medicare populations. It is imperative that CMS be proactive in working with other organizations and the stakeholder community to develop recommendations to address these concerns. CMS should also be encouraged to use their authority, through CMMI and other divisions, to better track the impact and use of opioids in Medicare populations— including the development of quality or incentive programs that track outcomes in patients who utilize non-opioid device-based alternatives in lieu of opioids.

CMS should promote patient access to care by trained specialists who can effectively prescribe and manage pain symptoms. A variety of health care providers including primary and pain physicians, neurologists, orthopods, physical medicine, emergency medicine, anesthesiologists, physical therapists, nurses and other specialists may be involved in making recommendations to patients regarding alternative means for treating their pain. These providers encounter and make care decisions for patients who could potentially benefit from an opioid alternative device. Therefore, it is critical that education regarding the epidemic, appropriate screening, opioid taper and discontinuation
(i.e. weaning), and treatment options (device, drug, combinations, and restorative therapy alternatives) be made known to all care providers. One way to accomplish the goal of educating these providers is through incorporation of information into the Welcome to Medicare Physical materials for both traditional and Medicare Advantage plans.

Provider education and sensitivity to the risk of opioid dependence is critical. Primary and other health care providers should be aware of the risk of their patients developing addiction issues and must be better informed of the treatment impacts that can be gained by using non-opioid devices. This will require more education regarding the range of devices and the appropriate time for their incorporation into patient treatment plans. It will also require provider education regarding the range of available device-based treatments; and education on the clinical approaches to “wean” patients from chronic oral opioids to non-oral opioid modalities for pain management.

It is important that the full spectrum of health care providers be updated regarding the latest technologies to use in treating chronic pain. Additionally, in the context of acute pain, it is equally as important to consider the risks and outcome impacts associated with the type of surgical technique that is utilized in treating a patient’s medical condition. For instance, patients may experience less post-surgical pain if treated with minimally invasive procedures when appropriate. The lower pain outcomes resulting from use of these less invasive procedures has been shown in studies to alleviate the need to prescribe opioids post-surgery. Additionally, patients with a history of chronic pain, lasting 6 months or more, should have access to non-opioid, interventional pain, therapies without coverage and reimbursement barriers.

AdvaMed recommends that CMS determine if additional education can be undertaken through updates disseminated via the Medicare Learning Network and other learning tools which educate and inform providers.

Additionally, it is important for care providers to have information regarding integrating these devices into the treatment process. AdvaMed agrees that this could be addressed though the integration of additional information into the medical school curriculum, including pain training in CME courses, opioid taper and discontinuation, and the dissemination and adoption of protocols, clinical practice guidelines, and information across sites of care. The Accreditation Council for Graduate Medical Education, HHS, and physician and nursing specialty societies could also work collaboratively to develop strategies for addressing training and education shortfalls.

Lastly, AdvaMed believes that it is imperative to educate Medicare beneficiaries regarding the alternatives available to them and the potential risks associated with opioid-based pain treatment. A first step in accomplishing this goal could involve updating the pain management information contained in the Medicare & You Handbook. AdvaMed
supports development of a public education campaign regarding acute and chronic pain awareness and treatment and welcomes the opportunity to engage in and support the development and roll-out of such a campaign if CMS decides to undertake such an effort.

**Conclusion**

AdvaMed supports CMS’s commitment to reduce inappropriate patient use of opioids by integrating device-based opioid alternative technologies and other approaches into the health care system so that patients, especially those at high-risk for SUD, can utilize them as soon as possible. We urge CMS to continue to work with payers and other entities to implement payment system and policy changes that ensure patient access to opioid device alternatives.

We would be pleased to answer any questions regarding these comments. Please contact DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can be of further assistance.

Sincerely,

Donald May  
Executive Vice President  
Payment and Health Care Delivery