AAFP
AMERICAN ACADEMY OF FAMILY PHYSICIANS

October 10, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Verma,

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write in response to the request for information for the development of a Centers for Medicare & Medicaid Services action plan to prevent opioid addiction and enhance access to Medication-Assisted Treatment (MAT).

The opioid crisis is a public health emergency that negatively impacts population health, community well-being, economic readiness, and social welfare. The rising number of opioid overdose deaths is both a symptom of our nation's health care challenges and a separate problem that requires urgent action. Family physicians have a unique opportunity to be part of the solution. Both pain management and substance use dependence therapies require longitudinal, patient-centered, compassionate care, which are consistent elements of primary care. The AAFP is actively engaged in the national discussion on pain management and opioid misuse. Committed to ensuring that our specialty remains part of the solution to these public health crises, the AAFP challenges itself and its members at the physician, practice, community, education, and advocacy levels to address the needs of a population struggling with chronic pain and/or opioid dependence. We encourage CMS to consult the AAFP's position paper "Chronic Pain Management and Opioid Misuse: A Public Health Concern" as the agency develops the action plan.

CMS invites the public to submit feedback regarding ways that CMS can help address the nation's opioid crisis through the development of an action plan.

Questions on Acute and Chronic Pain:

1. What actions can CMS take to enhance access to appropriate care for acute and/or chronic pain in Medicare and Medicaid, including

a. For special populations (for example, individuals with sickle cell anemia or individuals living in health professional shortage areas) and/or
b. Through remote patient monitoring, telehealth, and other telecommunications technologies?

AAFP Response

Investment in primary care is critical to ensuring access to appropriate care largely for Medicare and Medicaid populations. Family physicians conduct approximately one in five of the total medical office visits in the United States per year—more than any other specialty. Family physicians provide

comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families, and communities.

As a payer, CMS should implement policies that:

- Promote payment models to enable physicians to provide patient-centered, compassionate care in the treatment of chronic pain and opioid dependence and to appropriately compensate them for providing such care.
- Expand coverage of MAT in the primary care setting, with adequate reimbursement for the increased time, staff, and regulatory commitments associated with MAT.
- Expand access to naloxone and promote appropriate Good Samaritan protections for prescribers and lay rescuers.
- Work with state and federal licensing boards, the Drug Enforcement Administration (DEA), and the Substance Abuse and Mental Health Services Administration (SAMHSA) to destigmatize MAT, particularly in the setting of the community provider.
- Work with state and national partners to improve the functionality, utility, and interoperability of prescription drug monitoring programs (PDMPs) and develop best practices for their use and implementation.
- Expand research into the management of chronic pain, as well as methods to better identify and manage opioid misuse. Particular attention should be paid to vulnerable populations who are at higher risk for undertreatment of pain and/or for opioid misuse.
- Increase patient access to non-pharmacological pain therapies and non-narcotic pain medications by eliminating prior authorizations.

The AAFP believes telehealth can play an important role in treating and coordinating care for beneficiaries with opioid use disorders (OUDs). The AAFP agrees that the codes in the 2020 proposed Medicare physician fee schedule fall into Category 1 and should be added to the Medicare Telehealth Services list. CMS should also support telehealth to increase coordination between primary care physicians and pain specialists.

While acute and chronic pain should be managed by a multidisciplinary team, it is well recognized that pain complaints constitute a significant number of office visits each year. Despite filing this void, the country does not have a sufficient number of physicians to fill gaps in access. Therefore, the AAFP urges CMS to consider strategies that invest in primary care and includes strategies to grow the primary care workforce. For example, current policies regarding Medicare GME caps and funding has largely resulted in a decline in primary care residency slots. The Medicaid program is the second largest payer for GME and could be an importance resource to boost primary care training. Growing curricular elements and partnerships to ensure evidence-based, patient-centered acute and chronic pain management are essential to the curriculum in these programs will facilitate the type of care being delivered.

Another step CMS should take is to encourage the use of protocols for MAT to address opioid dependence within the clinic population. MAT for opioid and heroin dependence has existed for more than five decades and involves some form of opioid substitution treatment. Originally, only methadone (an opioid agonist) was available, but now clinicians have buprenorphine (a partial agonist used alone or in combination with naloxone) and naltrexone (an opioid antagonist with both oral and extended-release injectable formulations) as pharmacologic options for MAT. In addition, adjunctive medications such as clonidine, nonsteroidal anti-inflammatory medications (NSAIDs), and others are

used in the treatment of specific opioid withdrawal symptoms. We urge CMS to work with the Drug Enforcement Agency to eliminate the currently required waiver for prescribing buprenorphine to make it easier for physicians to prescribe this drug.

Finally, the AAFP looks forward to commenting fully on the Substance Abuse and Mental Health Services Administration's proposed rule titled "Confidentiality of Substance Use Disorder Patient Records." We support this proposed rule as it properly protects patient privacy concerns, improves the clarity of the law, and makes it less burdensome. Only in a setting of trust can a patient share the private feelings and personal history that enable the physician to comprehend fully, to diagnose logically, and to treat properly. The AAFP supports full access by physicians to all electronic health information within the context of the medical home.

2. 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? If answering this question, please provide information on how these policies have contributed.

AAFP Response
The AAFP has appreciated the opportunity to partner with CMS and looks forward to continuing to support the agency's efforts to advance payment models that are patient-centered and have a foundation in longitudinal, comprehensive primary care. However current health care systems and payment structures are fragmented, and do not adequately support the needs of patients struggling with acute and chronic pain. Copay costs associated with physical therapy sessions, lack of payment for evidence-based non-pharmacologic therapies such as massage and acupuncture, and administrative complexity within practices of knowing what medicines are or are not covered create inequities in care of patients struggling with both acute and chronic pain. These systems also do not uniformly address the financial barriers that patients may experience when accessing care, such as lack of transportation or delays in accessing physical therapy CMS should undertake a comprehensive process to review where patient's social and financial barriers undermine health care and treatment adherence.

Particularly focusing on patients with chronic pain or the prevention of patients with acute pain transitioning to chronic pain calls for greater overhaul of payment and coverage. Those with chronic pain often have suffered significant trauma and have elevated adverse childhood experience (ACE) scores. Studies suggest that up to two-thirds of patients with chronic pain has co-existing post-traumatic stress disorder (PTSD). Separation of physical and mental health benefits and limitations on integration of care under regulations largely affect care. While mechanisms of integrated behavioral health have been developed, coverage policies and payment do not provide sufficient support to practices to be able to hire and maintain the staff needed to integrate behavioral health into primary and specialty care settings.

As a result, the multimodal strategy to address pain that includes a biopsychosocial approach has been impeded by a system that does not adequately reimburse this approach for practices to be successful in doing so. Complicated administrivia often leave physicians unsure of where to send someone for counseling services external to the practice, particularly in shortage and rural areas. Even when individuals are connected, regulations limit communication to make care disconnected and disjointed.

3. 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?

AAFP Response
Current coverage policies promote non-opioid treatments for acute and chronic pain; however, this adds complexity to processes around prescribing opioids as opposed to enhancing or facilitating understanding around what non-opioid options are available. Options with proven efficacy for patients without a specific FDA indication (lidocaine patches) are often not covered despite the fact that many patients have trialed these medications in the past or had them administered in an inpatient setting and had relief. Trying to find formularies online that are constantly changing and rarely updated make it difficult to prescribe. Administrative complexity around coverage for non-preferred regimens make it incredibly challenging to deliver care. For example, the patient has trialed a preferred NSAID and failed and then needs prior authorization for another prescribed medication.

Another impediment is the limited public and private insurance coverage of MAT in the primary care setting, with inadequate reimbursement for the increased time, staff, and regulatory commitments associated with MAT. Nonpharmacologic treatment, including superficial heat, massage, acupuncture, or spinal manipulation, should be considered for coverage and reimbursement as well.

Prior Authorizations and insurance denials often impede non-narcotic and non-pharmacological treatment. According to a 2018 AAFP survey of members, in a typical week, almost half of respondents deal with prior authorization delays and insurance denials for non-narcotic or non-pharmacological pain treatment. A third of members surveyed deal with insurance denials for non-narcotic pain medication. This is a more prominent problem for rural family physicians than urban family physicians due to difficulties with adequate staff and affordable, functional electronic health record systems.

4. 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)?

5. What payment and service delivery models, such as those that utilize multimodal and multi-disciplinary approaches to effectively manage acute and chronic pain and minimize the risk of opioid misuse and OUD, could be tested by the Center for Medicare and Medicaid Innovation or through other federal demonstration projects?

a. What existing models, treatments or strategies identify and effectively manage the population of individuals misusing prescription opioids or using illicit opioids who then develop new or exacerbating pain?

AAFP Response to Questions 4 and 5
The AAFP is optimistic about CMS' recent announcement of the Primary Cares First (PCF) initiative and its potential to strengthen access to comprehensive and coordinated primary care. However, we continue to believe more Advanced APM options must be available to primary care physicians to

move the Medicare program towards value—especially for small and rural practices. The AAFP was one of the first organizations to successfully submit a model through the Physician-Focused Payment Model Technical Advisory Committee (PTAC). The AAFP's Advanced Primary Care Alternative Payment Model was approved by the PTAC in December 2017, receiving one of the strongest recommendations by the PTAC to date. Following approval of the APC-APM, the AAFP worked with CMS and the Innovation Center to inform the design of the Primary Care First (PCF) model. To effectively manage acute and chronic pain, the AAFP implores CMS to implement the AAFP's APC-APM proposal.

6. What can CMS do to better ensure appropriate care management for Medicare beneficiaries with pain who transition across settings, and/or between pain therapies?

AAFP Response
Family physicians are prepared to provide transitional care management (TCM) for patients in order to link patients with complex pain management needs back to a primary care physician. Unfortunately, due to a lack of communication between hospitals and other health care facilities with primary care physicians, the transmission or release of discharge information to the primary care physician often does not occur at all or does not occur within the two business days allotted to contact the patient as required by CMS to bill TCM. The AAFP believes CMS can help correct this situation by updating its rules and communications related to hospital discharge planning. The AAFP has previously supported CMS proposals to mandate that hospitals and other facilities better inform primary care physicians about the discharge of their patients in a timely fashion, which would help address the barrier family physicians encounter in attempting to use TCM codes within the two business days of discharge to contact the patient/caregiver.

Particularly for patients transitioning across settings, it is critical that approvals for medications and services remain intact such that individuals do not need new authorizations and approvals. Many times, patients are receiving services in inpatient settings or facilities that allow them to stabilize and return to a home or community-based setting.

7. How can Medicare and Medicaid data collection for acute and chronic pain better support coverage, payment, treatment, access policies, and ongoing monitoring?

AAFP Response
The AAFP supports implementation and encourages our members use prescription drug monitoring programs (PDMPs).

CMS should develop universal standards that must be followed by all plans including managed care plans. It is also critical to understanding the social needs of patients struggling with acute and chronic pain. As plans expand data collection on social determinants of health, understanding these needs among patients with acute and chronic pain are critical. Our system currently does not fund these social needs to a degree that facilitates successful treatment.

<u>Questions on Substance Use Disorders, including Opioid Use Disorders:</u>
1. What, if any, payment and coverage policies under Medicare and/or Medicaid for the treatment of SUDs, including MAT, do you believe, may help address the Nation's opioid crisis? If answering this question, please provide information on how these policies may help.

AAFP Response
As articulated in the AAFP's response to CMS on the 2020 proposed Medicare physician fee schedule, the AAFP supports the proposed Opioid Treatment Programs (OTPs) called for in the *Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act* (SUPPORT Act). It established a new Part B benefit category for OUD treatment services furnished by an OTP beginning on or after January 1, 2020.

However, current payment and coverage policies do not strongly encourage physicians to implement pharmacologic treatment for opioid use disorder (OUD) in their practices. SAMHSA grant funding helps fund states to develop mechanisms to expand access to buprenorphine largely through primary care and emergency room settings; however, few states have taken stances to ensure access to buprenorphine by all insurance carriers without prior authorization.

States are increasingly trying to regulate buprenorphine prescribing beyond the already restrictive regulatory process. Mandating counseling, which goes against recommendations from ASAM and SAMHSA, places limits on where and how people can obtain aftercare. Particularly in rural areas and HPSAs where limited behavioral health is available and not accessible, are largely affected by these restrictions and regulations. Current staffing within a medical practice fails to provide the needed social and behavioral health supports to provide OBOT. Lack of reimbursement for services of certified peer specialists and miniscule reimbursement for case management services by social workers do not facilitate sustainable practice models for many programs who initiate these services through grant funding or outside funding.

2. What, if any, payment and coverage policies in Medicare and/or Medicaid have enhanced or impeded the identification of, and access to the treatment by, beneficiaries with SUDs, including OUD?

AAFP Response
Most guidelines recommend screening patients to determine risks of drug misuse and abuse and to mitigate those risks as much as possible. Screening is typically based on risk factors that can be identified through a thorough patient history, the use of prescription drug monitoring programs (PDMPs), and, on occasion, drug screening. CMS should reimburse physicians for screening patients for SUD and OUD.

3. What evidence-based treatments, FDA-approved evidence-based medical devices, applications, and/or services that treat or monitor SUD, including OUD, monitor substance use withdrawal and/or prevent opioid misuse and opioid overdose are not covered, or have limited coverage, in Medicare?

AAFP Response
The cost of naloxone remains a significant barrier to access that perpetuates health inequity.

4. What payment and service delivery models that identify and treat people with pain who are at risk of, or have a past history of, OUD, could be tested by the Center for Medicare and Medicaid Innovation, or through other federal demonstration projects?

AAFP Response
Pennsylvania's Center of Excellence funding model to support practices that deliver this care should be featured and studied. An environmental scan should be conducted to identify other funding models that show improved health outcomes for patients at risk or with a history of OUD.

5. 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)?

AAFP Response
Current regulations around buprenorphine prescribing via telehealth limits its usability particularly in rural and shortage areas. Given restrictions around licensing and DEA across state lines, telehealth services that can provide essential access to these areas are unable to do so.

Furthermore, mobile buprenorphine programs are developing in many places across the country of different variability and context. Some are doing street-side initiation with transfer to a program while others are specifically managing through a mobile/street-side unit. This provides access to buprenorphine to a population who largely struggles with homelessness, of which 80% are interested in medication but do not have access through other means. Demonstration projects or opportunities to develop standards or best practices around these mechanisms would be very helpful to ensure that programs are not just developing that seek to help but actually harm communities. Furthermore, there are limits to providing methadone through mobile mechanisms given the federal moratorium on mobile methadone units. Particularly for rural and HPSA areas, this is particularly detrimental.

6. 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?

AAFP Response
As started earlier, CMS should expand telehealth opportunities and address buprenorphine restrictions across state lines to provide services in rural communities.

7. What recommendations do you have for data collection in Medicare and/or Medicaid
a. On the treatment of SUDs, including OUD, to better support coverage, payment, treatment, access policies, and ongoing monitoring, and/or
b. To facilitate research, policy development, and inform coverage and payment policies to prevent OUD?

AAFP Response
Data collection around treatment and prevention services are intricately linked. The areas hardest hit by the overdose crisis are areas entrenched in a history of policy wrought with problems – redlining, gentrification, disinvestment, poverty, and violence. The individual and community-level trauma that results creates circumstances that through understanding ACE data within communities, we can identify communities with high risk for development of substance use disorder.

Prevention efforts must be focused on transitioning our communities to be more trauma-informed and building optimal healing environments. This can start in schools and community centers. School-

based health centers can become foci to ensure that a trauma-informed culture is developed. While this concept has been promoted with theory and practice, systems do not yet support it. From a primary prevention standpoint, children in targeted communities are already affected by trauma. Secondary prevention though can focus on the ability to provide the child services through behavioral health with an ICD-10 code of elevated ACE or trauma that is reimbursed. As it stands now, many Medicaid systems cannot actually provide that child services until they actually have a diagnosis. Therefore, in many cases, diagnoses are made, labeling a child, causing further trauma to the child and their family, and our prevention efforts fail.

8. What recommendations do you have to lower prices of drugs used to reverse opioid overdoses (e.g., naloxone) for consumers?

AAFP Response
While not addressing drug costs to lower the cost of the opioid epidemic, the AAFP calls on CMS to promote greater patient access to cost effective alternative therapies (non-pharmacological, non-opioid). This includes major expansion and patient access to mental health services, pain management specialists, patient education, evidence-based interventions to identify those at risk for addiction, and increased support for prevention policies and programs.

Funding to specifically partner with health care institutions and practices and perhaps even pharmacies to provide naloxone should be available. If insurance does not cover adequately and the patient is unable to afford copay or cost, the medicine is provided to the patient and the provider/institution/pharmacy is reimbursed by such funding.

9. What other issues should CMS consider to improve coverage and payment policies in Medicare and Medicaid to enhance the identification of, treatment access by, and the treatment of beneficiaries with SUDs, including OUD?

AAFP Response
Mechanisms to cover the social needs of patients are critical. For many individuals, barriers to recovery are not simply access to buprenorphine, counseling, and treatment but rather housing, food insecurity, and transportation limitations. Recovery is further impeded by employment practices that stigmatize patients with substance use disorder who for many reasons have criminal records.

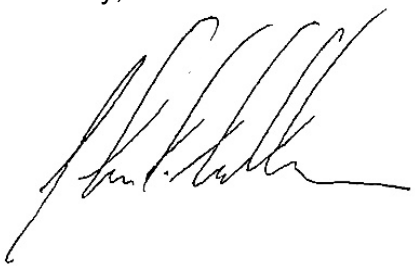
The AAFP calls for CMS to:

- Align residency program training to deliver evidence-based information on best practices in the management of chronic pain and opioid dependence.
- Promote and assist in funding for expanded continuing medical education (CME) offerings to deliver evidence-based information on best practices in the management of chronic pain and opioid dependence, including the appropriate use of naloxone.
- Expand the opportunities for DATA 2000 waiver training during residency. For mentoring and training purposes, this will ideally include faculty members at each residency site who are trained in MAT. Sites where waivered family medicine faculty members are not available should utilize collaborative teaching and mentoring arrangements with other providers.
- Expand the availability of waivered training courses at national, state, and regional CME meetings, as well as the availability of online and other alternative models of waiver training.

- Develop a list of DATA 2000-waivered family physicians across the United States who are willing to provide mentorship for newly waivered family physicians and residents, ideally with some form of reimbursement for their mentorship activities.

We appreciate the opportunity to provide these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 or rbennett@aafp.org with any questions.

Sincerely,



John S. Cullen, MD, FAAFP
Board Chair