AMERICAN ACADEMY OF
HOSPICE AND PALLIATIVE MEDICINE

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Robert R. Redfield, MD, Director
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30329

RE: Management of Acute and Chronic Pain: Request for Comment; Docket No. CDC–2020– 0029

Dear Dr. Redfield,

On behalf of the nearly 5,500 members of the American Academy of Hospice and Palliative Medicine (AAHPM), we would like to thank the Centers for Disease Control and Prevention (CDC) for inviting stakeholders to provide their perspectives on and experiences with pain and pain management, including their experiences managing pain, choosing among pain management options, getting information needed to make pain management decisions, and the benefits and harms of opioid use.

AAHPM is the professional organization for physicians specializing in Hospice and Palliative Medicine. Our membership also includes nurses, social workers, spiritual care providers, and other health professionals deeply committed to improving quality of life for patients facing serious illness, as well as their families and caregivers. The timely and effective management of pain and other distressing symptoms is central to providing these patients with high-quality palliative care, and opioid analgesics are a critical tool in alleviating that suffering.

AAHPM appreciates that the CDC's analysis of issues related to pain and pain management occurs in the context of a national crisis characterized by staggering rates of opioid use disorder and overdose death. At the same time, we must consider how best to ensure that the millions of patients with pain receive high-quality care, including treatment with opioids when they are medically indicated and can be taken safely.

AAHPM is particularly concerned with how best to balance the growing challenges related to managing pain with opioids with the need for ready access to appropriate pain medications for patients with serious or complex chronic illness and those at the end of life — patients for whom high-dose opioids may be necessary and medically appropriate. The Academy recognizes there is an indisputable public health imperative to curb opioid abuse, misuse, and diversion, and is deeply committed to both providing continuing education that results in optimal pain management and optimal care for all patients as well as to collaborating with professional, regulatory and industry stakeholders to maximize individual and public safety. However, AAHPM believes public policies must recognize there is an equally important public health imperative to ensure that our sickest, most vulnerable patients have access to timely, effective treatment of their pain and suffering. We are especially concerned about policies that limit opioid production, availability, and/or dosage and duration of prescriptions and would impede the individualization of treatment to patient needs. These efforts serve to paint all pain as the same and threaten access to appropriate care for patients with serious illness. We thus cannot emphasize strongly enough that a "one size fits all" approach is never appropriate.

AAHPM appreciates the CDC's attention to these challenges and applauds you for reaching out to stakeholders for information that may be useful in guiding the important work of leveraging public programs to help turn the tide on this epidemic. Our Academy's feedback on some of the CDC's questions follows below.

Understanding the Experience of Pain

Palliative and hospice care appropriately emphasize individualization of treatment, including analgesia for pain. Therefore, with regard to understanding a patient's pain, the CDC's request for input raises some concerns, particularly as its efforts are often predicated on distinguishing what is chronic vs. acute pain or cancer pain vs. non-cancer pain.

Categorizing a very diverse patient population with chronic pain into a group called "chronic non-cancer pain" lumps together subgroups – for example, low back pain patients who have not benefitted from multiple surgeries, advanced multiple sclerosis patients, and elderly patients with severe cardiac ischemia – that differ greatly, and mediators of individual risk, such as history of substance abuse, vary within each pain population.

We also know that the term "cancer pain" is vague when referring to the millions of patients who are long-term survivors. What is the demarcation point for cancer pain to non-cancer pain, especially as we consider patients for whom the disease is gone but the long-term consequences of treatment are very real? Cancer patients who suffer from chronic cancer-related pain can also suffer from acute and/or chronic pain that is unrelated to their cancer. Not only is it impossible and impractical to distinguish what proportion of these patients' pain is cancer-related versus how much is not related to cancer, it is also impossible to target systemic opioid analgesics such that they relieve only pain caused by cancer. Moreover, nociception is nociception, whether cancer related or not. The pathophysiology is the same. To put a distinction on who can have pain medicines by disease type thus ignores physiology.

Making Pain Management Decisions

Prescription Drug Monitoring Programs (PDMPs) — AAHPM supports the use of PDMPs as a clinical tool and believes prescribers can best determine when it makes sense to use program data, and thus avoid unnecessary burden to the provider team. To ensure the value of PDMPs, and in alignment with our Academy's own guidelines for effective PDMPs, we support EHR integration and interoperability that would allow for providers to access data across states and within and outside of federal health care entities. However, given that evidence is lacking to support when PDMP data is best used and there exist limitations on accessibility of such data, we have serious concerns about quality measurement tied to PDMP queries. Finally, as Hospice and Palliative Medicine specialists typically work to support a patient's other healthcare providers, we note the importance of pharmacists understanding that physicians often work as part of teams and that "doctor shopping" is a conclusion that should only be made after a pharmacist has made contact with the provider. (Many of the above concerns are highlighted in this discussion of a Quality Improvement project examining PDMP queries at a cancer center's palliative care clinic.)

Screening and Monitoring — As AAHPM acknowledges both the value of and the lack of evidence for some screening tools, we believe that the use of such tools should be determined by the prescriber considering the individualized patient circumstances and characteristics. For example, mandating patient treatment agreements would be inappropriate for hospice patients with a prognosis of days or weeks, so any policies intended to apply universally should include appropriate exemptions for patients in hospice with no identified risk factors for opioid abuse or diversion. In addition, as a growing number of states

legalize recreational marijuana, we highlight as a gap the lack of research and guidance for clinicians that encounter a positive THC on a urine screen in a state where marijuana is legal.

Overdose Prevention — AAHPM supports efforts to expand availability of naloxone but notes that co-prescribing and dispensing must be clinically appropriate. We therefore would urge that any guidance regarding naloxone co-prescribing/dispensing include carve-outs for patients at the end of life. In addition, efforts aimed at patient and family education should also be expanded to include provider education on whether/when naloxone is appropriate. For example, an Academy leader relays having seen naloxone given to a dying cancer patient on high-dose opioids because a well-meaning EMT misinterpreted the decline associated with dying as being opioid overdose. This resulted in ICU admission for a hospice patient who went into complete opioid withdrawal while simultaneously unmasking all their opioid-managed pain.

Opioid Use Disorder — Individuals with opioid use disorder (OUD) may suffer with a serious or terminal illness and require palliative or hospice care – including opioid treatment. AAHPM would be deeply concerned if federal guidance or policy served to preclude prescribing opioids to these patients or restrict coverage or reimbursement for appropriate opioid use for individuals suffering from OUD. Not providing appropriate pain management for a patient suffering from OUD who is seriously ill would have dire consequences, including the patient potentially seeking relief in illicitly obtained opioids and other narcotics.

Utilizing Non-Pharmaceutical Therapies for Chronic Pain When Clinically Appropriate

AAHPM appreciate the CDC's interest in nonpharmacological approaches to pain management expressed in its request for comments. As a field, we recognize the value of and seek to encourage coordinated and collaborative care. This includes a multimodal and multidisciplinary approach to pain management. In two convenings of the Integrative Pain Care Policy Congress, our Academy joined dozens of organizations representing healthcare providers, public and private payers, policy experts, and pain research and patient advocacy organizations to consider joint strategies for advancing individualized care for people with pain. Participants developed and worked from the following consensus definition: "*Comprehensive integrative pain management (CIPM) includes biomedical, psychosocial, complementary health, and spiritual care. It is person-centered and focuses on maximizing function and wellness. Care plans are developed through a shared decision-making model that reflects the available evidence regarding optimal clinical practice and the person's goals and values."* AAHPM believes that the domains of palliative care naturally track with this vision.

Unfortunately, there are no reimbursement mechanisms for most nonpharmacological interventions. A successful multidisciplinary approach to pain necessarily requires consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate; for psychological and behavioral health interventions (including through alternative treatment delivery, such as telehealth); and for complementary and integrative therapies that have been shown to be effective for pain management. We thus urge the CDC to work with the Centers for Medicare & Medicaid Services (CMS) and private payers, encouraging them to cover multimodal and nonpharmacological pain treatment where these are options; otherwise, prescribers will necessarily default to treatments, like opioids, that are reimbursed in order to ensure their patients' pain is managed. Further, the CDC could urge the Food and Drug Administration to prioritize and accelerate approval of adjuvant analgesics to decrease the need for opioids.

Expanding Pain Research

AAHPM believes we must develop a better understanding of the mechanisms of pain and urges the CDC to work with federal partners to address the acute need for more research on safe and effective treatments

for pain, which our Academy has pointed to through a provision in the Palliative Care and Hospice Education and Training Act (H.R. 647 / S. 2080). Congressional support will be essential to improve funding for pain research and to direct relevant agencies to better coordinate ongoing research efforts. In addition, we suggest that the CDC recommend that policymakers ease current barriers to medical research on cannabinoids.

Educating Prescribers

AAHPM believes it is critical to elevate the knowledge of appropriate prescribing of controlled substances across various providers and medical specialties, and to ensure prescribers are appropriately trained to manage risks for opioid misuse and diversion and knowledgeable in safe storage and disposal. To that end, AAHPM is a founding member of the Collaborative for Relevant Education, or CO*RE, which was initially formed to develop and disseminate REMS-compliant training in safe prescribing of long-acting/extended-release opioids and has since updated its curriculum to address the CDC Guideline and include immediate-release opioids. A recording of AAHPM's "Opioid Prescribing: Safe Practice, Changing Lives" webinar is offered free on our Academy website. A volume of AAHPM's *Essential Practices in Hospice and Palliative Medicine* is also focused on Pain Assessment and Management. This book presents the latest in assessing malignant and non-malignant pain, total pain, nociceptive and neuropathic pain, opioid conversions, common side effects of pain treatment, and non-opioid adjuvant medications.

In addition, our annual conference routinely features sessions on topics such as managing pain in opioid-dependent patients and guidelines for methadone safety and effectiveness in hospice and palliative care, with recordings available after the meeting for those unable to attend in person. Through the American Medical Association (AMA) Opioid Task Force – of which AAHPM is a member – our Academy was also invited to assist the AMA in developing an interactive CME product on pain management.

Despite this commitment to prescriber education, AAHPM remains opposed to *mandated* CME, particularly as the effectiveness of mandates has not been well established. Today, practitioners may face multiple state requirements for continuing education covering such topics as suicide or domestic violence screening, infectious disease, and cultural competence and, as such, end up less engaged and simply "checking the boxes" to obtain the required credits. Therefore, we believe more research is needed to determine the actual impact of mandated CME on provider behaviors, treatment access, and patient outcomes. That said, any requirement for provider education in this area may be best operationalized by requiring practitioners who request DEA registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registration or renewal.

Overall, we would caution that, as more training and practice burden is placed on practitioners, it is unknown what effects theses mandates, coupled with new guidelines and payer policies, will have on clinician interest or feasibility to care for the complex population of patients with pain, particularly those on opioids. Numerous overlapping policies and guidance for practitioners that aim to stem the crisis of opioid abuse and overdose death have already had a cooling effect on prescribing by primary care providers, with these practitioners confused and in fear of retribution for prescribing opioid analgesics. In fact, we have seen such unintended consequences as physicians trying to get their non-terminal patients into hospice so the hospice can take over prescribing of opioids and overall pain management. To ensure there are no such further unintended outcomes, prescriber education must be properly targeted and incentivized, so practitioners actually learn when opioids are appropriate along with best practices for prescribing them, rather than opt out of doing so altogether.

Targeting Prescribing Patterns

Particularly since the CDC published its opioid prescribing guidance in 2016, there has been an emphasis within state and federal programs on identifying "high prescribers" of opioids. AAHPM is concerned that this broadly demonizes "high" prescribing when, in fact, patient-centered care would recognize that pain will not only differ by condition but by the individual (different patients have different pain thresholds) and their history and circumstances (e.g. complications in treatment). Patients with pain are not all the same, so managing pain effectively and safely requires an individualized approach based on many factors, including pain syndrome, patient risk factors, underlying illnesses, life expectancy, clinical expertise, degree of control and monitoring available to the treatment team, and appropriate goals of treatment (for many patients not just relief of pain, but also optimal physical and mental function, preserved work and family role, quality of life, and survival). Especially when taking care of individuals with serious and life-limiting illness, we must be able to carefully titrate interventions to the circumstance unique to that patient. The primary goal should be ensuring a patient's pain and other distressing symptoms are adequately controlled.

This effort to identify "high prescribers" is based on the assumption that "high prescribing" equals "bad prescribing." However, for some specialties, high prescribing patterns may be the norm and completely appropriate. For other specialties, even low prescribing may be inappropriate and not indicated. We thus urge the CDC and other policymakers to instead focus on *inappropriate* prescribing patterns of opioids. Many of AAHPM's members would be considered "high" prescribers, but not inappropriate prescribers. This is because of the patients we treat: many palliative and hospice patients have acute symptoms from non-cancer terminal illnesses and require more than 100 mg of morphine equivalents per day for sufficient pain and symptom control and, depending on the underlying mechanism of pain and degree of development of opioid tolerance, some require much higher doses. By contrast, if an internist were to prescribe most of his or her patients more than 100 mg of morphine equivalents per day, this should raise concern and warrant a closer look, as an internist's patients are not all seriously or terminally ill. For this reason, Medicare and Medicaid claims that provide information on patient diagnosis could provide better indicators of inappropriate prescribing than simply looking at the *volume* of prescriptions written.

Updating the 2016 CDC Guideline

Should the CDC move forward with updating and/or expanding its Guideline for Prescribing Opioids for Chronic Pain published in 2016, we would look for the CDC to engage in a transparent process that includes an adequate opportunity for stakeholder review and comment. We further urge the CDC to adopt a patient-centered approach in evaluating best practices and to ensure there is strong evidence to support any recommendations.

The 2016 Guideline has been broadly misapplied, with devasting effect on patients and prescribers. Forced tapering of patients' opioid prescriptions has been incentivized and/or mandated, violating ethical and evidentiary norms of medical practice. This has resulted in many patients' medical deterioration, loss of care relationships, turning to illicit substances/alcohol, and suicidality. Swapping products and formulations to reduce opioid prescriptions where not medically necessary has also led to medical errors. At the same time, prescribers have faced professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the morphine milligram equivalent (MME) thresholds included in the CDC Guideline.

Looking ahead at a possible update to the CDC Guideline, AAHPM's key concern would be continuing guidance that aims to limit the dosage and duration of prescriptions. There is no scientific basis to support

calls to restrict the dosage and duration of opioid treatment for pain, and AAHPM objects to such considerations as they would unduly burden patients with serious and life-threatening illness. As a population, these patients typically need higher doses of opioids, often for long periods. Limits on allowable daily dosages can thus result in uncontrollable pain and symptom crises for patients that could otherwise be managed by an amount of medicine that is arbitrarily discouraged.

Severe limits on the duration of prescriptions are also burdensome for seriously ill individuals, particularly those being treated in an outpatient setting. Patients suffering moderate-to-severe chronic pain are often those least capable of meeting the increased hurdles that Schedule II drugs carry. These patients frequently have limited mobility and must be accompanied by caregivers. Requiring office visits with greater frequency simply to obtain a prescription is an even greater hurdle for those living in rural or underserved areas as their healthcare provider may be hours away. Furthermore, and perhaps most critical, access to these medications often has substantial bearing on these patients' quality and length of life, as it allows them to complete their disease-directed treatments, sleep through the night, or continue to work and otherwise engage in daily activities. AAHPM believes a better solution is to encourage prescribers and pharmacists to embrace partial fill policies for their patients. Such action would better target the proliferation of large amounts of unused medications which are a contributor to the opioid crisis.

Any updates to federal guidance also must recognize the unique needs of special populations, including both pediatric and geriatric patients, for whom pain management education and guidelines are lacking. Further, AAHPM notes there are striking health disparities across racial and ethnic populations as well as for patients with specific conditions, such as sickle cell disease, that should be considered. Similarly, general guidance may not be appropriate for patients with a limited prognosis (as often encountered in hospice and palliative care) and patients who are cognitively impaired. Both patient populations have chronic medical problems and are likely to receive treatment with opioids, and they are frequently managed by practitioners who do not specialize in pain or palliative care.

In summary, palliative and hospice care appropriately emphasize individualization of treatment, including analgesia for pain, and AAHPM would oppose any CDC recommendations that would preclude an individualized approach to patients' legitimate needs. Moving forward, it must be clear that CDC recommendations should be just one of a number of rational considerations that prescribers use to guide treatment, along with evidence for best practices and an individual's unique circumstances and goals of care. Unfortunately, the reality today is that recommended restrictions have been inappropriately adopted as rules and codified in statute. Moreover, while the CDC's 2016 recommendations are meant to apply to primary care outside of cancer, palliative and end-of-life care, health systems, pharmacy benefit managers and payers are in fact using the CDC Guideline to impose limits on opioid prescriptions regardless of a patient's diagnosis or goals.

Finally, we urge the CDC and its federal partners to consider how to better evaluate the impact of any revised guidance, beyond just tracking the amount of medication prescribed. As just one consideration, AAHPM suggests incorporating patient-reported outcomes in such a review. For example, as part of the Palliative Care Measures Project, AAHPM is partnering with the National Coalition for Hospice and Palliative Care and RAND to create a patient reported experience measure to assess the extent to which adult patients receiving outpatient clinic-based palliative care received the help they wanted for pain. (The project, which will conclude September 2021, is a cooperative agreement between CMS and AAHPM as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).) A balanced approach to assessing opioid efficacy and safety would consider more than just prescribing patterns and include such measures of the patient's quality of life.

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Thank you again for inviting stakeholders to provide insight into pain management and the current barriers to achieving optimal, patient-centered care for patients with pain. Setting aside its financial costs, unrelieved pain causes inordinate human suffering resulting in longer hospital stays, increased readmissions and outpatient visits, and decreased ability to function or enjoy quality of life. AAHPM therefore greatly appreciates the opportunity to provide this feedback, and we stand ready to serve as a partner in achieving balanced policy that maximizes individual and public safety while ensuring patients receive timely, appropriate treatment for their pain and suffering. Please address questions or requests for further information to Jacqueline M. Kocinski, MPP, AAHPM Director of Health Policy and Government Relations, at jkocinski@aahpm.org or 847-375-4841.

Sincerely,

Rodney O. Tucker, MD MMM FAAHPM
AAHPM President