



AMERICAN ACADEMY OF
HOSPICE AND PALLIATIVE MEDICINE

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April 11, 2022

Rochelle P. Walensky, MD MPH, Director
Centers for Disease Control and Prevention
4770 Buford Highway NE
Atlanta, GA 30341

Re: Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids [Docket No. CDC-2022-0024]

Dear Director Walensky:

On behalf of the more than 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 the opportunity to comment on the proposed *CDC Clinical Practice Guideline for Prescribing Opioids – United States, 2022* (2022 Guideline).

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 critical to providing these patients with high-quality palliative care, and opioid analgesics are an important tool in alleviating that suffering.

AAHPM appreciates that the CDC's analysis of issues related to pain management and opioid prescribing occurs in the context of a national crisis characterized by staggering rates of drug-related overdose and 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.

Our Academy 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 misuse and diversion, and we are deeply committed to both providing continuing education that results in optimal pain management and optimal care for all patients and to collaborating with professional, regulatory and industry stakeholders to maximize individual and public safety. At the same time, AAHPM believes public and payer 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 have serious concerns regarding policies that aim to 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 and all patients as the same and threaten access to appropriate care for patients with serious illness.

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 circumstances unique to that patient. The primary goal should be ensuring a patient's pain and other distressing symptoms are adequately controlled.

Increasingly, however, we have seen how well-intentioned but misguided policies that rely on arbitrary, across-the-board opioid prescription limits can lead to unintended, and often devastating, consequences for patients and families. Unfortunately, the *2016 CDC Clinical Practice Guideline for Prescribing Opioids* (2016 Guideline) served as the basis for such policies far too often. As CDC acknowledges, misapplication of the 2016 Guideline resulted in policies and actions that have contributed to a wide array of patient harms, including but not limited to untreated and undertreated pain, serious withdrawal symptoms, psychological distress, and suicidal ideation and behavior. Notably, such policies arose despite language in the 2016 Guideline specifying that its recommendations were voluntary.

Given this history, AAHPM believes that great care should be taken in rolling out the final 2022 Guideline to ensure that unintended consequences and risks of patient harm are minimized. We recognize that CDC proposed changes to the 2016 Guideline with such a goal in mind and, in many regards, changes incorporated into the draft 2022 Guideline succeed in advancing that goal. However, we believe that significant risks remain for patients who may require higher opioid doses, like patients with serious illness or who are at the end of life. While we acknowledge that the CDC exempted patients receiving palliative or end-of-life care from the recommendations included in the proposed 2022 Guideline, we note that the same was true with the 2016 Guideline, which nonetheless was misapplied and resulted in significant harm for such patients as well as some prescribers. We also have concerns with the process CDC undertook in developing the draft 2022 Guideline, which we believe has suffered from a lack of transparency and numerous conflicts of interest. As such, we feel compelled to offer more detailed feedback below to strengthen the 2022 Guideline and minimize potential harms to the patients and families our members serve.

Ongoing Risk of Harm

AAHPM appreciates the CDC's recognition that the 2022 Guideline requires a more flexible, person-centered approach to opioid prescribing than was included in the 2016 Guideline. This approach is apparent in many of the key messages included in the proposed 2022 Guideline, including in the introductory summary box and the overall guiding principles. We particularly applaud language included in the introductory summary box which highlights that the Guideline is not a replacement for clinical judgment nor intended to be applied as inflexible standards of care, as well as in guiding principle 2, which notes that the recommendations are voluntary and intended to support individualized, person-centered care and that flexibility to meet the care needs and clinical circumstances of a specific patient are paramount. We also appreciate the emphasis in guiding principle 4, warning against the risks of misapplying the guideline beyond its intended use or implementing policies derived from the guideline that might lead to unintended consequences.

However, previous experience with the 2016 Guideline highlights the ongoing risk of misapplication of the revised Guideline, which could continue to result in patient harm. At a high level, ***we are concerned that the proposed 2022 Guideline overall takes an unbalanced approach towards assessing the risks and benefits of opioid prescriptions, with an excessive focus on the risks of opioids and relatively little attention to the potential benefits for patients in need of significant pain management, including patients with serious illness.***

Indeed, in its preliminary review of the 2022 Guideline, the Board of Scientific Counselors of the National Center for Injury Prevention and Control's Opioid Workgroup noted that "much of the supporting text of the guideline was not balanced and was missing key studies" and "the guideline focused heavily on the risks or potential harms of opioids, while less attention was focused on the potential benefits of opioids, or the risk of not taking opioids or undertreating pain."

AAHPM believes that language throughout the 2022 recommendations reflects this bias. For example, when the Guideline recommends that "[c]linicians should **only** consider initiating opioid therapy if expected benefits ... are anticipated to outweigh risks to the patient" [emphasis added], the use of the term "only" in this and similar recommendations is prejudicial. It discourages consideration of opioid therapies while, at the same time, the recommendation re-states an obvious tenet to which clinicians should always adhere in making any treatment decision, whether for opioid prescribing or otherwise – that is, to weigh risks against benefits. We also worry that terms like "only" that are definitive in nature further increase the risk of potential misapplication of the 2022 Guideline, and we therefore suggest limiting their use in the context of the recommendations and implementation considerations throughout the revised Guideline.

In addition to the overall tenor of the Guideline, we also are concerned with specific language that could result in targeted harms. For example, we are concerned that clinicians may inappropriately apply the Guideline to patients with serious illness who would benefit from – but may not be able to access – specialty palliative care. We are also concerned with language suggesting that 50 morphine milligram equivalents (MME)/day could serve as a threshold for limiting opioid dosages, even if such language is not included in the formal recommendation. We discuss both of these concerns in greater detail below. We also note that there is nothing in the proposed Guideline that can mandate against its misapplication, and there are no consequences for misapplying the Guideline. Furthermore, there is no language in the proposed 2022 Guideline that urges federal and state policymakers, health plans, pharmacies, or other actors to reverse policies based on the misapplication of the 2016 Guideline. Harmful policies that remain tied to the 2016 Guideline will continue to impose barriers to medically necessary opioid-based pain management.

Given these considerations, ***AAHPM recommends that CDC take concrete steps to mitigate the potential harms that could arise as a result of the 2022 Guideline – as well as those that have resulted from the 2016 Guideline. These include:***

- ***Denouncing policies based on arbitrary dosage thresholds included in the 2016 Guideline, and including language in the 2022 Guideline urging policymakers, health plans, pharmacies, and other stakeholders to rescind such policies.***
- ***Discussing the risk that misapplication of the 2022 Guideline can result in patient harm, including in the introductory summary.***

- *Including a disclaimer on every page of the 2022 Guideline that the clinical guidance is voluntary and should not be deemed a standard of care or inflexible threshold, and that treatment decisions should be based on clinicians' judgment of patients' individual circumstances and clinical needs.*
- *Engaging in promotion efforts that emphasize the voluntary, non-binding nature of the Guideline and the prioritization of individualized, person-centered care.*

We believe such steps, at a minimum, are necessary to protect our patients against unintended consequences that we are certain will otherwise arise with the misapplication of the 2022 Guideline.

Guideline Development Process

As noted above, AAHPM has concerns with the process CDC undertook in developing the draft 2022 Guideline, including its lack of transparency and conflicts of interest. In particular, we are concerned that the organization Health Professionals for Responsible Opioid Prescribing (PROP) – which has a clear anti-opioid bias – has had a disproportionate influence on the development and content of the proposed 2022 Guideline. A well-known PROP ally is listed as an author of the Guideline and lead researcher on several CDC-funded reviews conducted by the Agency for Healthcare Research and Quality (AHRQ) and then cited as supporting evidence for the Guideline. We believe this has led the Guideline to be overly skewed against opioids, with little discussion of the benefits of opioid treatments. These conflicts ultimately undermine the integrity of the 2022 Guideline. We believe greater transparency is necessary to support the adoption of a clinical guideline that carries the weight and reach that the 2022 Guideline will inevitably have. Further, given the expectation that CDC will continue to regularly update this and other guideline documents, *it is imperative that CDC better review and manage conflicts of interest to ensure that ensuing recommendations can be trusted.*

We also have concerns regarding the transparency and completeness of the peer review process. While CDC notes that peer review is required, CDC had yet to complete the peer review process prior to issuing the proposed 2022 Guideline and did not provide a definitive date for when the peer review process would be complete. Therefore, it is not clear to what extent the recommendations may change following peer review. Furthermore, it does not appear that the public will have an opportunity to comment on peer-reviewed recommendations if they do result in significant changes. Additionally, CDC has failed to report on the identities or conflicts of interest of the peer reviewers prior to public review and comment, further raising transparency concerns.

We also disagree with CDC's approach to including stakeholders in the Guideline development process, including with respect to selection of individuals to participate in the Opioid Workgroup. To our knowledge, there were no representatives from the palliative care community who served on the Workgroup, despite AAHPM having submitted a highly qualified nominee. While we recognize that the Guideline exempts patients receiving palliative care, as noted above, our members and their patients were significantly harmed by the 2016 Guideline, and input from our perspective could have helped to inform a revised Guideline to better center the needs of patients who require high doses of opioids. Again, *ensuring the inclusion of the full range of stakeholders in important deliberations moving forward would serve to strengthen the integrity of future recommendations.*

Finally, we have serious concerns about the quality of evidence used to inform the proposed Guideline's recommendations and implementation considerations. Like the 2016 Guideline, seven out of 12 recommendations in the proposed 2022 Guideline are based on the lowest quality evidence, and three additional recommendations are based on the second lowest quality evidence, yet they will drive opioid prescribing practices for years. This is particularly problematic when the Guideline references specific opioid dosages that may be used as thresholds for limiting opioid prescriptions. Additionally, we note that, in many instances where the Guideline referenced limited available evidence on the benefits of opioid treatments, it failed to note the reasons why data were limited – for example, limitations of conducting opioid studies for extended periods. ***We therefore urge CDC to more clearly identify the quality of evidence used to inform recommendations throughout the discussion, as well as to de-prioritize recommendations based on lower quality evidence and to provide greater context for why evidence may be limited or unavailable.***

Applicable Population

AAHPM appreciates that the proposed 2022 Guideline clearly specifies the population to which the final Guideline will apply, and we agree that treatment for sickle-cell disease-related pain, cancer pain, palliative care, and end-of-life care should remain outside the purview of the Guideline. However, ***we are concerned that many patients with serious illness or pain that limits functional status for whom surgical interventions are not indicated – especially those who may require high doses of opioids to manage their pain – may not technically fall under the Guideline's exemptions as currently written because they are not being treated by a palliative care specialist.***

There are key [disparities](#) with respect to access to and utilization of palliative care and hospice services, including across racial and ethnic groups and geographic locations. A major barrier to resolving such disparities is the documented [shortage](#) of trained hospice and palliative care providers and the [insufficiency](#) of current training programs to meet the demand for palliative and hospice care consistent with the expected growth in the population of patients who will require such care. These access challenges thus raise equity concerns as well. These patients who may be unable to access specialty palliative care will yet require a different approach to opioid prescribing than that envisioned under the proposed Guideline. ***We therefore urge CDC to update the Guideline to clarify that patients with serious illness receiving primary palliative care are also exempt from the Guideline's recommendations.*** Furthermore, we note that even patients receiving specialty palliative care may be difficult to identify, for example through claims-based identifiers like Z codes that payers may apply to manage opioid misuse. This again raises concerns that the Guideline may be misapplied to limit access to opioid prescriptions for patients who require palliative care and underscores the need for CDC to take action to mitigate such harm.

Additionally, while we recognize and agree that the Guideline should not apply to care delivered in inpatient settings, we note that the Guideline has the potential to affect patients treated in such settings, nonetheless. For example, some prescribers may refrain from prescribing higher doses of opioids, whether or not such doses may be clinically appropriate, simply due to concerns about a patient's ability to continue the same dosage level upon discharge. More commonly, patients may receive higher dosage opioid prescriptions in the hospital, but they then experience difficulties with pain management following discharge when primary care practitioners may be unwilling or unable to manage these dosage levels. Our members report these challenges have been tied to the 2016 Guideline, which had an overall cooling

effect on prescribing by primary care providers, many of whom were left confused and/or 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 admitted into hospice so that the hospice can take over prescribing of opioids and overall pain management. To address these types of scenarios, ***we recommend that CDC consider developing an evidence-based clinical practice guideline for patients in inpatient settings as well as those transitioning from inpatient to outpatient care.***

Finally, we appreciate that CDC clarifies that use by pain management specialists is not the focus of the 2022 Guideline, and that the balance of risks and benefits to patients might differ when the treating clinician is a pain management specialist treating patients with complex pain conditions. Again, however, caution will be needed to protect against overly broad application of the Guideline that might otherwise restrict these specialists' prescribing practices.

Definition of Palliative Care

In the proposed 2022 Guideline, CDC notes that the Guideline follows the Institute of Medicine's definition of palliative care as "care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness." Because this definition comes from a report focused on the end of life, the definition included the qualifier "advanced" illness. However, widely accepted definitions of palliative care do not limit this care to only advanced illness or comfort care but recognize that palliative care can be provided from the time of diagnosis for patients facing serious, but not terminal, illness. For example, we refer CDC to the [National Consensus Project's Clinical Practice Guidelines for Quality Palliative Care](#), which have been endorsed by over 90 organizations. The National Consensus Project defines palliative care as follows:

Beneficial at any stage of a serious illness, palliative care is an interdisciplinary care delivery system designed to anticipate, prevent, and manage physical, psychological, social, and spiritual suffering to optimize quality of life for patients, their families and caregivers. Palliative care can be delivered in any care setting through the collaboration of many types of care providers. Through early integration into the care plan of seriously ill people, palliative care improves quality of life for both the patient and the family.

AAHPM therefore urges CDC to remove "advanced" from its definition of palliative care when the 2022 Guideline is finalized, and to consider more comprehensive definitions like the one promulgated by the National Consensus Project. Such a definition will also help to clarify that patients receiving primary palliative care fall under the Guideline's palliative care exemption.

Draft 2022 Recommendations

Recommendation 1

Nonopioid therapies are effective for many common types of acute pain. Clinicians should only consider opioid therapy for acute pain if benefits are anticipated to outweigh risks to the patient (recommendation category: B, evidence type: 3).

AAHPM generally agrees with Recommendation 1 and its promotion of non-opioid therapies for acute pain, except for our concern noted above regarding the use of the word "only" in the formal recommendation. ***We recommend that CDC remove the word "only" from the formal recommendation.***

Recommendation 2

Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients the known risks and realistic benefits of opioid therapy, should work with patients to establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks (recommendation category: A, evidence type: 2).

AAHPM agrees with Recommendation 2 that nonopioid therapies are preferred for subacute and chronic pain, but *we again raise concerns with the use of “only” in the formal recommendation and urge CDC to remove it from the formal recommendation.*

AAHPM also supports the emphasis on shared decision-making with patients, including discussions of risks and benefits and goals for pain and function. However, it may be worth noting that this may not always be possible, such as for patients who have cognitive impairment. We particularly appreciate the suggestion that patient preferences and values should be discussed and understood and used to inform clinical decisions. Towards this end, AAHPM has worked with stakeholder experts, patients, and caregivers to develop [two new patient reported experience measures](#) that assess quality of care provided by asking how much patients felt heard and understood and if patients got the help they wanted for their pain. CDC may wish to reference these within the Guideline’s implementation considerations.

Finally, as a field, hospice and palliative care recognizes the value of and seeks to encourage coordinated and collaborative care. This includes a multimodal and multidisciplinary approach to pain management. We thus appreciated the robust discussion of non-pharmacologic approaches to pain management under this recommendation and support the call for health insurers and health systems to increase access to noninvasive, nonpharmacologic therapies with evidence for effectiveness. The need for reimbursement mechanisms for these interventions is particularly important, including 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. These treatments must be covered by Medicare, Medicaid and private payers if they are to become mainstream and accessible. Further, such coverage should come with limited to no utilization management restrictions, such as prior authorization, which result in significant burden for clinicians and delayed or denied care for patients. Without timely access to nonpharmacologic treatments, prescribers will necessarily default to treatments, like opioids, that are readily reimbursed in order to ensure their patients’ pain is adequately managed.

Recommendation 3

When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4).

While we generally agree with the substance of Recommendation 3 and its implementation considerations, which focus on initial use of immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids, we offer the following recommendations to further strengthen its message:

- **Reframe the recommendation to increase clarity.** We believe the following language would more clearly state our understanding of the recommendation: “*When starting opioid therapy for acute, subacute, or chronic pain, immediate-release opioids should initially be prescribed prior to initiation of extended-release/long-acting (ER/LA) opioids, if needed.*”
- **Delete the fifth implementation consideration,** which reads, “*Although there might be situations in which clinicians need to prescribe immediate-release and ER/LA opioids together (e.g., transitioning patients from ER/LA opioids to immediate-release opioids by temporarily using lower dosages of both), in general, avoiding the use of immediate-release opioids in combination with ER/LA opioids is preferable, given the potential increased risk for adverse events, including respiratory depression and overdose.*” We note that concurrent use of IR and ER/LA opioids is generally considered the standard of care for patients who are experiencing cancer pain. While we recognize that the Guideline is not intended to apply to such patients, we are concerned that this language is likely to be misconstrued and applied across the board to all patients, particularly given our experience with the misapplication of the 2016 Guideline.

Recommendation 4

When opioids are initiated for opioid-naive patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest dosage to achieve expected effects. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully evaluate individual benefits and risks when considering increasing dosage, and should avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients (recommendation category: A, evidence type: 3).

While AAHPM appreciates that the formal recommendation considers individual patient needs and does not include a threshold dosage level, *we have significant concerns regarding the discussion under Recommendation 4, particularly references to 50 MME/day as a dosage above which benefits may diminish or risks may accelerate.* We recognize that CDC states that recommendations are not intended to be used as an inflexible, rigid standard of care for starting opioids; however, we still worry that the inclusion of a dosing level – along with language focusing on risks of doses above that level – will inevitably lead some readers to view 50 MME/day as a hard dosing threshold, similar to how the 90 MME/day dosage from the 2016 Guideline was viewed and consequently incorporated into harmful public and payer policies. Yet, despite the known harms that resulted from including the 90 MME/day threshold in the 2016 Guideline, CDC has again included a new – and substantially lower – dosing threshold in the proposed Guideline revision. Moreover, this lower dosing threshold would not provide sufficient flexibility to titrate doses as needed for patients who may require more intensive pain management. We believe this is irresponsible and problematic for many reasons.

To begin, there is no evidence to support the use of MME as a basis for limiting opioid dosages and no reliable standardized way to calculate MMEs across different opioid active ingredients, formulations, and dosages. Moreover, we disagree that the literature supports conclusions about risks of higher opioid dosages or the absence of benefits above 50 MME/day. Many of the studies that have found relationships between higher opioid dosages and risk of overdose are low-quality studies with methodological challenges. And lack of evidence of the benefits of higher dosages simply suggests that additional research is needed to more carefully study the effects of higher dosages on outcomes of interest, including patients’ pain, function, and psychological well-being. In other words, that relevant data does not exist does not equate to evidence to substantiate a lack of benefit. Indeed, given the complexities of managing pain for patients with serious illness, our members are often required to rely

on “n of 1 trials” for individual patients who have unique needs that are not well captured by available evidence, varying opioid dosages on a case-by-case basis to contend with the uncertainty posed by lack of evidence and to nevertheless identify effective treatments and dosages to manage pain. Basing the Guideline’s recommendations and accompanying implementation considerations – which largely serve to further refine the recommendations and offer additional guidance – on such sparse and poor-quality data yet again reflects the underlying anti-opioid bias in the Guideline and raises real risks for patients who will require high doses of opioids to manage their pain.

As a point of comparison, we refer CDC to the [Interagency Guideline on Prescribing Opioids for Pain](#), developed by the Washington State Agency Medical Directors’ Group (AMDG). Here the AMDG discusses potential risks associated with higher doses of opioids, but clearly does not establish low dosage limits (e.g., at the 50 MME/day level), presumably to enable continued clinician judgement in determining appropriate, individualized pain treatment. Instead, the AMDG advises consultation with trained pain specialists before increasing dosages above a much higher 120 MME/day threshold.

The MME thresholds discussed in the implementation considerations don’t just risk inappropriate treatment for patients with pain, they could lead to stigma for patients being appropriately managed on higher doses and pose risks to prescribers as well. Clinicians 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 MME thresholds included in the 2016 CDC Guideline. So, we have serious concerns that continuing to even suggest such thresholds could invite more of the same.

Given the above, *AAHPM urges CDC to remove any references to numerical dosing thresholds (e.g., 50 MME/day) in the proposed 2022 Guideline’s Recommendations or Implementation Considerations that could be misinterpreted and perceived as limits to guide dosing decisions. CDC should also make clear that evidence pertaining to the use of doses or quantities to establish a prescribing threshold is categorized as low-quality, and therefore any doses or quantities referenced in the proposed Guideline should not serve as the basis for any laws or policies.*

Recommendation 5

For patients already receiving higher opioid dosages, clinicians should carefully weigh benefits and risks and exercise care when reducing or continuing opioid dosage. If risks outweigh benefits of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper to lower dosages or, if warranted based on the individual clinical circumstances of the patient, to appropriately taper and discontinue opioids. Unless there are indications of a life-threatening issue, such as warning signs of impending overdose, e.g., confusion, sedation, or slurred speech, opioid therapy should not be discontinued abruptly, and clinicians should not abruptly or rapidly reduce opioid dosages from higher dosages (recommendation category: B, evidence type: 4).

AAHPM generally supports Recommendation 5 and appreciates the clear guidance against nonconsensual tapers to lower opioid dosages. However, we suggest two changes to help strengthen CDC’s tapering guidance:

- *Reframe the recommendation to reflect that the goal of tapering should be to achieve the lowest effective opioid dose that is appropriate to patients’ unique situations and pain management needs, which may in some cases include discontinuation of opioids, as already noted in the recommendation. In our view, the current framing overemphasizes tapering down to full*

discontinuation of opioid utilization, rather than focusing on individual patients' pain management goals and needs.

- *Add a separate implementation consideration that directly addresses the scenario where patients initiate a taper but then develop recurrent pain with lower dosages. In such cases, the CDC should be clear that reversing tapers would be appropriate to achieve the lowest effective opioid dose to achieve desired pain reduction and control.*

Recommendation 6

When opioids are needed for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids (recommendation category: A, evidence type: 4).

AAHPM supports Recommendation 6 and particularly appreciates the avoidance of any specific dosing thresholds in the recommendation or implementation considerations.

Recommendation 7

Clinicians should evaluate benefits and risks with patients within 1 to 4 weeks of starting opioid therapy for subacute or chronic pain or of dose escalation. Clinicians should evaluate benefits and risks of continued therapy with patients every 3 months or more frequently (recommendation category: A, evidence type: 4).

AAHPM is concerned that Recommendation 7 and its accompanying implementation considerations could lead to unintended consequences for patients requiring pain relief – particularly those requiring doses above 50 MME/day. The repeated references to 50 MME/day as a threshold dosing level in the implementation considerations could lead to the application of hard dosing thresholds that, as we note above, have resulted – and are likely to continue to result – in significant patient harms. As such, we do not believe the benefits of including references to specific dosage thresholds outweighs the risks. Paired with requirements to evaluate patients on a specified schedule – as included in the formal recommendation – a threshold dosing level could result in limits at the pharmacy, with pharmacies only dispensing a week's supply of opioid prescriptions at a time. In addition, for many patients, more frequent evaluations may also come with additional co-pays and co-insurance, the need to take time off from work or household obligations, and other burdens that are not imposed on patients with other chronic disease.

Given the above, *AAHPM recommends that CDC eliminate all references to numerical dosing thresholds under this recommendation and its implementation considerations. We also recommend that CDC remove references to appropriate intervals for patient follow-up, revising the text to suggest evaluation and follow-up "at appropriate clinical intervals determined by the clinician."*

Recommendation 8

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss with patients. Clinicians should work with patients to incorporate into the management plan strategies to mitigate risk, including offering naloxone when factors that increase risk for opioid overdose are present (recommendation category: A, evidence type: 4).

AAHPM generally supports Recommendation 8 and believes that CDC's discussion and implementation considerations offer strong guidance across a number of issues. At the same time, **we offer the following suggestions to further strengthen this recommendation:**

- ***Remove the reference to 50 MME/day included in the first implementation consideration as an example of a high opioid dosage.*** As noted above, we are concerned that specified values in the recommendations and implementation considerations could be viewed as hard dosing thresholds, which should be avoided. We also note that – for many patients, including many with serious illness – 50 MME/day would not be viewed as a high dosage, and including this reference could lead to stigma for patients being appropriately managed on higher doses.
- ***Update guidance in the sixth implementation consideration, which recommends avoiding prescribing opioids to patients with moderate or severe sleep-disordered breathing when possible, to specify that it apply to “patients with untreated moderate or severe sleep-disordered breathing.”*** Treatment of sleep-disordered breathing, for example with a CPAP machine, can significantly mitigate the risk of opioid adverse effects.
- ***Add an implementation consideration clarifying that patients who are actively dying may present in a manner that could be mistaken for overdose and that, for such patients, naloxone will result in harm.*** For example, an Academy leader relays having seen naloxone given to a dying 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 patient who went into complete opioid withdrawal while simultaneously unmasking all their opioid-managed pain. While we recognize that the Guideline does not apply to patients receiving end-of-life care, we believe this is a phenomenon that is not well known or understood, and that greater education and awareness could help to reduce harms that would otherwise arise if such a mistake were made.

Recommendation 9

When prescribing initial opioid therapy for acute, subacute, or chronic pain, and periodically during opioid therapy for chronic pain, clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or combinations that put the patient at high risk for overdose (recommendation category: B, evidence type: 4).

AAHPM supports Recommendation 9 and the use of PDMPs as a clinical tool to mitigate patient harm, and we believe 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, ***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, and we recommend that CDC work to guide state and federal policies to achieve this goal.*** However, given that evidence is lacking to support when PDMP data is best used, and there exist limitations on accessibility of such data, ***we suggest CDC include a caution against quality measurement tied to PDMP queries.***

Finally, we note the rise in patients being improperly questioned and/or denied medication fills by pharmacies. It is important to consider that, as a patient begins opioid therapy, there may be incremental changes to the dose and/or quantity prescribed along with the type of opioid analgesic by itself or in combination with other pharmacologic options. Those adjustments may be interpreted by a state PDMP and/or pharmacist as a new “start” and wrongly flagged as “doctor shopping.” In addition, physicians often work as part of teams, and prescriptions may be appropriately issued from more than one provider. ***We thus urge CDC to add a caution to its implementation discussion to note that “doctor shopping” is a conclusion that should only be made after a pharmacist has made contact with the provider.***

Recommendation 10

When prescribing opioids for subacute or chronic pain, clinicians should consider toxicology testing to assess for prescribed medications as well as other prescribed and non-prescribed controlled substances (recommendation category: B, evidence type: 4).

AAHPM acknowledges both the value of and the lack of evidence for some screening tools and finds there is significant complexity associated with administering toxicology testing for patients receiving opioid therapies. For example, there is considerable risk of bias in toxicology testing that can lead to disproportionate harm, so AAHPM applauds the third implementation consideration, which cautions against applying this recommendation differentially based on assumptions about what may be learned about different patients. Furthermore, when toxicology testing is conducted, there is often a great deal of uncertainty regarding how clinicians should respond to findings; this includes positive findings related to marijuana use, which is further complicated by changing state and local laws regarding the legal status of marijuana and its use for medical purposes. To better address this complexity in the formal recommendation – in a manner that is comparable to the treatment of this issue in the implementation considerations – *we recommend updating Recommendation 10 to read as follows: When prescribing opioids for subacute or chronic pain, clinicians should consider the risks and benefits of toxicology testing to assess for prescribed medications as well as other prescribed and non-prescribed controlled substances.* We believe this change better ties the recommendation and its implementation considerations together, while also acknowledging the challenges that exist with respect to toxicology screening.

We also highlight that a major barrier and burden associated with toxicology testing is the out-of-pocket cost to patients. Depending on the type of test used, as well as the frequency of testing, patients may be responsible for significant cost-sharing for toxicology testing. Further, given the bias noted above, excessive cost sharing is likely to fall disproportionately on patients of color and patients from low socioeconomic backgrounds. To address this issue, *we recommend that CDC include guidance specifying that insurers should increase coverage of toxicology testing to mitigate the burden and eliminate barriers associated with toxicology testing.*

Recommendation 11

Clinicians should use extreme caution when prescribing opioid pain medication and benzodiazepines concurrently and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants (recommendation category: B, evidence type: 3).

AAHPM supports Recommendation 11 and believes it provides sufficient flexibility to clinicians to prescribe opioid medications concurrently with benzodiazepines, as necessary and appropriate to manage patients' individual care needs.

Recommendation 12

Clinicians should offer or arrange treatment with medication for patients with opioid use disorder (recommendation category: A, evidence type: 1).

AAHPM appreciates CDC's attention to the important issues surrounding opioid use disorder (OUD) and the 2022 Guideline's discussion of how best to support patients, including clinicians' direct involvement in medication-assisted treatment. Our Academy is an active member of the American Medical

Association's Substance Use and Pain Care Task Force and contributed to the development of that group's 2021 [recommendations](#) which include a focus on removing barriers and improving access to evidence-based care for patients with pain and/or a substance use disorder. Earlier task force recommendations also track with CDC's guidance as they focused on the need for physicians to become trained to better identify and treat opioid use disorder as part of an overall goal of improving patient outcomes and reducing stigma for patients with pain and those with an OUD.

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Thank you again for the opportunity to comment on the proposed 2022 Guideline and share our members' experience with pain management and understanding of 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,

A handwritten signature in black ink that reads "Tara C. Friedman, MD FAAHPM". The signature is written in a cursive, flowing style.

Tara C. Friedman, MD FAAHPM
AAHPM President