April 11, 2022

To: National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE
Mailstop S106-9
Atlanta, GA 30341

Attn: Docket No. CDC-2022-0024

To the Respected Reviewers at the Centers for Disease Control and Prevention:

We, the undersigned members of the Alliance to Advance Comprehensive Integrative Pain Management (AACIPM), are writing to you in response to CDC's draft Clinical Practice Guideline for Prescribing Opioids—United States, 2022 (hereinafter, the "2022 Guideline").

AACIPM is a multi-stakeholder collaborative comprised of non-profit organizations and subject matter experts representing people living with pain, public and private insurers, patient and caregiver advocates, researchers, purchasers of healthcare, policy experts, and 37 professional and trade organizations representing the full spectrum of healthcare providers. These diverse experts are united in a shared interest to advance access to a value-based, person-centered model of integrative pain care focused on maximizing function and wellness that includes biomedical, psychosocial, complementary and integrative health, and spiritual care. It is with this unique perspective that the undersigned members of AACIPM respectfully offer the following comments.

AACIPM is grateful for CDC's efforts to thoughtfully consider the impact that the 2016 Guideline had on people living with pain as it works to update and refine the 2022 Guideline prior to its finalization. In reviewing the proposed 2022 Guideline, it is clear to us that CDC valued the respected and varied experts that made up its Opioid Workgroup, and we believe the proposed recommendations are much stronger for their inclusion in the development process.

We wish to offer our support for the following additions and/or changes to the 2022 Guideline:

- **Removal of Dosage Thresholds (aka "Ceilings") and Stronger Emphasis on Patient-Centered Care –**
  We applaud CDC's decision to remove specific morphine milligram equivalent (MME) dosage thresholds from its recommendations. The 50 MME and 90 MME thresholds from the 2016 Guideline were never intended by CDC to be dosage ceilings; however, as CDC has long-acknowledged, these thresholds were often misinterpreted and misapplied by clinicians and policymakers, with many people living in pain consequently suffering needless titration and/or abandonment. We are grateful to CDC for replacing these recommendations (#5 in the 2016 Guideline, #4 and #5 in the 2022 Guideline) with language that better educates the reader about evaluating risk and benefit (at any dosage) throughout the course of treatment while preserving room for clinical judgment and avoiding potential confusion regarding MME thresholds.

- **Emphasis on Non-Opioid, Non-Pharmacological, and Integrative Therapies and Acknowledgment that Reimbursement is a Significant Barrier –** As an alliance that comes together in support of comprehensive integrative pain management, we sincerely appreciate CDC's continued support of the use of a wide variety of pain management therapies, including a number of evidence-based non-pharmacological approaches. However, until public and private payment structures adequately cover these types of care, they will remain woefully inaccessible due to a number of interrelated barriers, including geographic and socioeconomic factors.

  We thank CDC for acknowledging that multimodal therapies are not always available or reimbursed by insurance, and, moreover, for explicitly stating that health systems and public and private payers should work to ensure these treatments are available, accessible, and reimbursed. Currently, a number of therapies discussed

by CDC as alternatives to opioids—that are notably included in many pain-related guidelines—often remain elusive for people who can benefit from them. Many evidence-based services delivered by professionals who are trained to provide non-opioid care are not approved for reimbursement by the Centers for Medicare & Medicaid Services (CMS), even when the care is within the provider's scope of practice. This includes, but is not limited to, services provided by: acupuncturists, advanced practice registered nurses, chiropractors, physical therapists, occupational therapists, and massage therapists. This artificially reduces patient access to the care they can provide. Further significant barriers to patient access include high co-pays, under-reimbursement, and inequitable care for people who are underserved.

This is a multi-faceted and challenging issue that is regularly discussed by participants in our alliance of leaders representing people with pain, providers, payors, academia and more; consequently, we know how imperative it is to include a wide variety of stakeholders in the conversation when identifying solutions. To effect optimal implementation of CDC's recommendations, AACIPM urges CDC to establish a multi-stakeholder working group to more fully understand the gamut of barriers faced by patients seeking pain care. Ideally, CDC would partner with CMS on this working group; if not, we urge CDC to share its findings with CMS.

- **Explicit Intention that the 2022 Guideline is Voluntary and Not an Inflexible Standard of Care –** We strongly and emphatically thank CDC for including language within the 2022 Guideline that explicitly states that it provides voluntary clinical practice recommendations that should not be used as inflexible standards of care and that it is not intended to be implemented as absolute limits by policy organizations, healthcare systems, third-party payers, or government entities. When CDC released the draft of their original opioid guideline in late 2015, advocates in the area of pain policy expressed their concerns that the recommendations would be misconstrued by policymakers as black and white rules with no room for individualized care and professional judgment. In the years since, these fears have often proven to be valid, with countless state legislatures, licensing boards, and insurers adopting portions of the guideline as law or policy, as opposed to recommendations, and nearly always in ways that ignore the nuance and flexibility of the underlying guideline in favor of strict dosage ceilings and duration limits never intended by CDC. We thank CDC for this clarification (currently found on Page 5, Lines 83-87), and we <u>urge that it be presented prominently</u> within any and all dissemination materials created by CDC upon final release of the 2022 Guideline (see our discussion of Box 1, below).

In the spirit of multistakeholder collaboration, and in furtherance of delivering safe and effective pain management, AACIPM would also like to offer a number of ways that we believe the 2022 Guideline and/or its related dissemination efforts could be improved.

Recommendations #1 and #2:

While AACIPM is very much in support of the spirit of recommendations #1 and #2, we believe there are a number of minor-but-impactful ways these recommendations can be improved.

It is our understanding from reading the 2022 Guideline, and these recommendations specifically, that for acute, subacute, and chronic pain, CDC is (1) advocating for the use of non-opioid therapies as a first-line approach, and (2) stating that clinicians should only consider opioid therapy if expected benefits are anticipated to outweigh the risks to the patient. However, the recommendations for acute pain (#1) are currently listed separately from subacute and chronic pain (#2), which could lead the reader to assume there is a difference between first-line approaches for the three types of pain, despite the recommendation for each remaining essentially the same. Evidence-based non-opioid and, often, non-pharmacologic, modalities should be the first line of treatment beginning in the acute phase.

Further confusing matters, Recommendation #2 (relating to subacute and chronic pain) states that clinicians should discuss treatment goals and eventual discontinuation with a patient "before starting opioid therapy" while

Recommendation #1 (relating to acute pain) says no such thing. This is problematic, because (1) opioid therapy is often initiated during the acute phase, not the subacute/chronic phase, with transition to a new phase being gradual, and (2) it implies that no discussion of treatment goals and eventual discontinuation is required if prescribing for acute pain.

Too often, non-opioid approaches are not sought early enough or are relegated to the final attempt to manage pain, markedly reducing their chances of providing pain relief. Thus, in an effort to best guide and educate the clinicians who will use the 2022 Guideline, we believe that, rather than creating an arbitrary distinction between acute and subacute/chronic pain, it would be more logical to use Recommendation #1 to address non-opioids being first-line treatment and Recommendation #2 to discuss initiating opioid therapy.

We are also concerned by CDC's use of "preferred" in Recommendation #2, and we would strongly recommend using "first-line approach" in its place. The terms "preferred" and "non-preferred" are standard terminology within the health insurance industry related to coverage and reimbursement. While CDC is not in a position to directly regulate insurers, its guidance does ultimately impact public and private policies, including insurance coverage. Knowing this, we do not think it appropriate to use terminology that could so easily be misconstrued and misapplied by insurers. Further, we believe "first-line approach" is more reflective of medical terminology, which is appropriate for the clinical audience for which this guideline is intended.

Finally, while we strongly support recommending the use of non-opioid therapies as a first-line approach to managing pain, we also carry with us a stark understanding that many clinicians lack an adequate "toolbox" of non-opioid pain management techniques. Further, while we appreciate CDC's inclusion of supplemental information related to a variety of pain management modalities within the 170-page document, it is very likely that the vast majority of clinician's will only ever be presented with the 12 main recommendations, leaving them without the helpful supplemental information.

To improve the chances of educating clinicians and improving care delivery, we suggest that Recommendation #1 be accompanied by a diagram and/or table of possible non-opioid approaches—a "Pain Management Toolbox." Specifically, we encourage CDC to utilize either (1) the well-vetted work that has already been completed by HHS in its *Pain Management Best Practices Inter-Agency Task Force Report (2019)* by incorporating Figure 6: Individualized Patient Care Consists of Diagnostic Evaluation That Results in an Integrative Treatment Plan That Includes All Necessary Treatment Options, or (2) a related and more detailed diagram that was developed by our multistakeholder alliance to build awareness about the multidisciplinary team and self care as part of an effective, multimodal, comprehensive treatment plan (see below for both diagrams).

AACIPM is sincerely grateful for the efforts CDC has taken to highlight the effectiveness of a wide variety of non-opioid and non-pharmacologic therapies for pain management, and we stand ready to aid in the effort to educate providers, payers, patients, and more about the many types of evidence-based pain management therapies and how they may be best utilized within individual treatment plans. We would be honored to aid CDC in further developing a "Pain Management Toolbox" for providers in order to help better implement Recommendations #1 and #2, and we thank you for considering its inclusion within the 2022 Guideline.

We suggest the following as alternate language for recommendations #1 and #2:

Recommendation #1: Non-opioid therapies, including a wide range of evidence-based, non-pharmacological complementary modalities, are effective for many types of acute, subacute, and chronic pain and should be a clinician's first-line approach. Clinicians should only consider opioid therapy for pain management if non-opioid therapies are expected to be ineffective based on the patient's unique condition, medical history, prior experience with these modalities, and the provider's clinical decision making.

Clinicians should familiarize themselves with a variety of non-opioid and non-pharmacological methods of pain management, as each patient may require a unique combination of therapies.

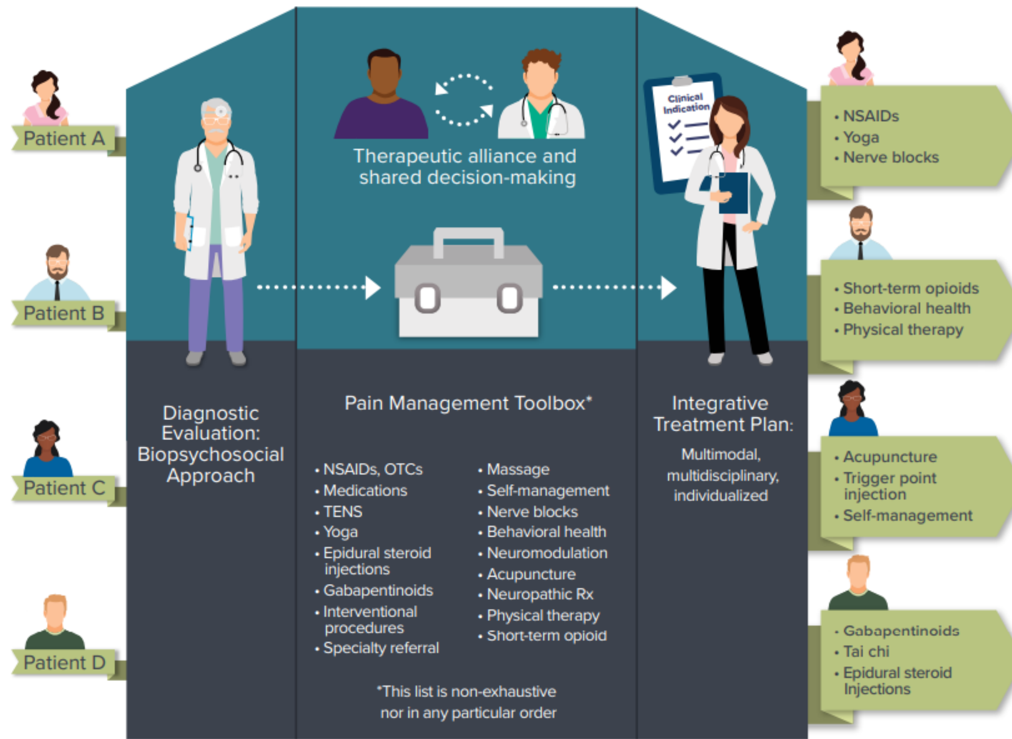

Figure 6: Individualized Patient Care Consists of Diagnostic Evaluation That Results in an Integrative Treatment Plan That Includes All Necessary Treatment Options

U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

1. Diagnostic Evaluation	2. Interdisciplinary Alliances & Shared Decision-Making	3. Development of Comprehensive Treatment Plan	Patient Care Team Members	Treatment
Biopsychosocial evaluation with initial provider	Pain Management Toolbox *non-exhaustive • Acupuncture • Aquatherapy • Biofeedback • Care Partner • Case management • Chiropractic • Counseling/Pain Psychology • Health Coaching • Massage Therapy • Medication (e.g., OTCs, gabapentinoids, neuropathic medications, shortterm opioids) • Nursing • Nutrition and Dietetics • Pharmacology • Occupational Therapy • Pharmacology • Physical Therapy • Procedures (e.g., injections, nerve blocks) • Social Work • Support groups • Tai chi • TENS • Yoga Self-care and Self-management: Can be a combination of provider-directed and self-directed and can include tools from the list above.	Evaluation with identified care providers Collaboration with patient	**Patient A with** • Neurologist • Dietitian • Physician assistant	**Patient A's Plan:** • Nerve blocks • Personalized meal plan • Community-based support group • Self-management: Schedule rest after nerve blocks; Shopping IADLs for meal plan; Initiate contact with support group
			Patient B with • Rheumatologist • Occupational therapy practitioner • Acupuncturist	**Patient B's Plan:** • Gabapentinoids • Activity Pacing • Improve sleep and rest routines • Acupuncture • Self-management: Develop consistent medication regimen; Identify and implement sleep hygiene modifications; Time management for scheduling regular acupuncture visits
			Patient C with • Primary care provider • Physical therapy practitioner • Counselor	**Patient C's Plan:** • TENS • Home exercise program • Cognitive behavioral therapy (CBT) • Self-management: Adhere to prescribed TENS routine; Time management and activity pacing for home exercise; Utilize CBT materials for self-reflection
			Patient D with • Pain management specialist • Nurse practitioner • Pain psychologist	**Patient D's Plan:** • Community-based yoga • Trigger point injections • Biofeedback • Self-management: Identify preferred yoga class and teacher; Practice techniques learned in biofeedback sessions; Maintain injection schedule

Adapted from: U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

Recommendation #2: 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 pain management, 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.

Unclear Presentation of the Twelve Recommendations:

While the members of our alliance appreciated CDC's thoughtfulness and attention to detail within the 170 pages of the 2022 Guideline (not including references, disclosures, etc.), we found it difficult to easily identify the twelve main recommendations. We are concerned that this will also be true of the clinicians for whom the guideline is intended. Currently, the actual recommendations do not even begin until Page 60, and even then, they are scattered over the next hundred pages. Upon careful inspection of the 2022 Guideline, we found that "BOX 1" on page 208-210 contains just the twelve recommendations and the five guiding principles. This information would be better suited at the very top of the document. It is practical and fair to assume that most actively-practicing clinicians will not have the time to read hundreds of pages of guidance, and Box 1 represents the core of the recommendations—the baseline information that CDC will want every clinician to be aware of before prescribing opioids for pain management.

We strongly urge CDC to move the information found in Box 1 to the top of the 2022 Guideline.

"Rescinding" Rather than "Updating" the Guideline and Adequate Dissemination Efforts

We are grateful for the changes made in the 2022 Guideline, as we believe that CDC is taking appropriate, and much-needed, steps to undo damage that was inadvertently caused by the 2016 Guideline. However, because the 2016 Guideline was so widely misunderstood and misapplied, and because the 2022 Guideline so significantly works to undo those wrongs, we urge CDC to fully ***rescind*** the 2016 Guideline rather than merely issuing "updates" with the 2022 Guideline. Calling the changes to this guideline a mere "update" fails to convey what serious mistakes were made with the prior version, nor does it convey that individuals and entities should immediately cease relying upon it as the basis for their current policies. Further, the greatly expanded applicability of the 2022 Guideline to not only physicians, but also to nurse practitioners, physician assistants, and oral health practitioners, illustrates that the 2022 Guideline is truly a new approach to pain management as opposed to a mere update.

In the years since the 2016 Guideline was issued, at least 33 states have adopted statutory limits on opioid analgesic prescriptions[1]—limits caused by the perceived "ceilings" in the 2016 Guideline. While many of these statutes have explicitly set specific MME limits, others incorporate the 2016 Guideline by reference; in the latter, CDC could right a number of wrongs by simply rescinding the damaging guidance to which these statutes cite. Even now, despite the impending release of the 2022 Guideline, the Iowa Board of Medicine is in the process of implementing a continuing education mandate related to the 2016 Guideline, meaning each and every one of their licensees will be taught outdated information if the Board isn't apprised of the issue so they can take appropriate action.[2]

Adequate dissemination and education efforts are vital if CDC is to truly use the 2022 Guideline to right the wrongs created by the 2016 Guideline. Rescinding the 2016 Guideline would cause sufficient media attention to alert many clinicians and policymakers who would have otherwise missed the general roll out of the 2022 Guideline. However,

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[1] Prescribing Policies: States Confront Opioid Overdose Epidemic. National Conference of State Legislatures. June 30, 2019. Available at: https://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx. Accessed March 28, 2022.

[2] Chronic Pain and End-of-Life Training. Iowa Board of Medicine. Available at: https://medicalboard.iowa.gov/chronic-pain-and-end-life-training. Accessed March 28, 2022.

whether CDC ultimately decides to rescind or simply issue updates, a number of dissemination and education efforts should be considered:

- The 2016 Guideline was rolled out with much fanfare and extensive presentations, a package of materials to every state public health department in the nation, and the issuance of grants to consultants to develop materials related to guideline dissemination. We hope to see commensurate measures taken for the 2022 Guideline, as well as substantial measures targeted at clinicians themselves, such as webinars and easy-to-understand fact sheets.
- An online resource for training and FAQs, possibly set up in collaboration with HHS, FDA, and/or the NIH HEAL Initiative.
- Online resources related to the vast spectrum of non-opioid and non-pharmacological methods of pain management, and when these modalities may be indicated for particular patients, perhaps based on the Pain Management Best Practices Inter-Agency Task Force Report and AHRQ systematic reviews.
- Identification of, and outreach to, specific individuals, organizations, payers, and health systems that can help CDC to promote change in service organization and delivery.
- An online portal for reporting problems with policymakers and/or health systems who are misapplying the guideline, enabling CDC to immediately follow-up and respond to misunderstandings and misapplications, ensuring active efforts are being taken to educate policymakers who continue to misapply CDC's Guideline.
- Outreach to non-profit organizations representing people with pain to introduce them to the portal for reporting problems, which will help to rebuild public/patient support of CDC's Guideline.

AACIPM remains an ally in support of CDC efforts to improve pain management delivery and opioid prescribing, and we stand ready to collaborate on dissemination of the forthcoming guidelines.

Thank you for the work you have invested in developing the 2022 Guideline and for considering our recommendations.

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