C-TAC
COALITION TO TRANSFORM ADVANCED CARE

1299 Pennsylvania Avenue NW
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April 11, 2022

To: Angela K. Oliver, Executive Secretary, Centers for Disease Control and Prevention

Re: CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022

On behalf of the Coalition to Transform Advanced Care (C-TAC), we appreciate the opportunity to provide comments on the sections of the revised CDC Clinical Practice Guideline for Prescribing Opioids regarding their effect on those living with serious illness.

C-TAC is a national non-partisan, not-for-profit coalition dedicated to ensuring that all those living with serious illness, especially the sickest and most vulnerable, receive comprehensive, high- quality, person- and family-centered care that is consistent with their goals and values and honors their dignity. C-TAC is made up of over 190 national and regional organizations including patient and consumer advocacy groups, practitioners, health plans, faith-based and community organizations, and others who share a common vision of improving care for serious illness in the U.S.

Overall, we support these revised guidelines but have serious concerns with continuing to include warnings about MME dose ceilings. We also find the current guidelines format not ideal for clinical use in that information is difficult to access, duplicated, and nested within the various recommendations. Chapters, bullets, graphics would help in this regard. See below for more specifics following the order of the guidelines document:

Scope and Audience- Excluded Populations

We appreciate that pg. 14 of the revised guidelines continue the excluded populations from the previous guidelines of those with "sickle cell disease-related pain management, cancer pain treatment, palliative care, and end-of-life care"[i]. Of course, not all with serious illness are able to access palliative or hospice care, so there are still those in that population who would be covered under these guidelines and might get suboptimal pain management as a result. We wonder if the guidelines could be revised to note that this, and other populations living with significant pain, like musculoskeletal conditions, may benefit from opioids when other modalities are unsuccessful[ii].

Palliative Care Definition

We also appreciate the use of the definition of palliative care on pg. 18 from the Institute of Medicine's 2015 as "care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness. Palliative care can begin early in the course of treatment for any serious illness that requires advanced management of pain or other distressing symptoms". Many are unaware[iii] that palliative care can be offered along with

all disease-modifying or curative treatment so this definition clarifying that is helpful. While palliative care is not directly indicated for those living with chronic pain, it is appropriate for those with serious illness who may also have pain or other painful conditions.

Evidence-based/Key Themes

We appreciate that the recommendations note the quality of evidence and address the key themes of "strained patient-provider relationships and the need for patients and providers to make shared decisions, the impact of misapplication of the 2016 CDC Guideline, inconsistent access to effective pain management solutions, and achieving reduced prescription opioid use through diverse approaches" (pg. 62). The misapplications of the 2016 guidelines have been a problem for those living with serious illness who need access to FDA-approved opioids to maintain their function and quality of life.

Recommendation Guiding Principles

We support the guiding principles on pg. 63 with the following comments:

Acute, subacute, and chronic pain need to be appropriately and effectively treated independent of whether opioids are part of a treatment regimen. We support this approach since pain is often a prominent symptom in patients with malignant and nonmalignant serious illness[iv] and one that significantly affect their lives and the lives of those who help care for them. Opioids are just one way to treat pain and should be considered when medically appropriate.

Recommendations are voluntary and are intended to support, not supplant, individualized, person-centered care. Flexibility to meet the care needs and the clinical circumstances of a specific patient are paramount. This is a critical point, and we strongly support it. People with serious illness need person-centered care that involves being informed about their illness to facilitate shared decision making for treatment decisions. This process should be personalized, and no guideline should interfere with what the person and their health care provider decide is appropriate care for them.

A multimodal and multidisciplinary approach to pain management attending to the physical health, behavioral health, long-term services and supports, and expected health outcomes and well-being of each person is critical. We would agree and ideally people with pain should get interdisciplinary, team-based care to facilitate this approach, such as palliative care if they also have a serious illness.

Special attention should be given to avoid misapplying this updated clinical practice guideline beyond its intended use or implementing policies purportedly derived from it that might lead to unintended consequences for patients. This addresses the unintended and, in some case, tragic effects[v], of the misapplication of the previous guidelines. Our concern going forward, however, is how the CDC will work to avoid such future misapplication, since it occurs at all policy levels of health care down to that of individual providers and facilities.

We recommend that any dissemination of the revised guidelines include this point about misapplication and the unintended harms that has and can cause.

Clinicians, practices, health systems, and payers should vigilantly attend to health inequities, provide culturally and linguistically appropriate communication including communication that is accessible to persons with disabilities, and ensure access to an appropriate, affordable, diversified, coordinated, and effective nonpharmacologic and pharmacologic pain management regimen for all persons. The inequity in pain management and opioid use[vi] has been another unfortunate consequence of the previous guidelines and we support the effort to ensure that medication management is appropriate for all with pain, especially those groups who have historically gotten less care and inadequate pain control.

Comments on Additional Guideline Elements

Adjuvant medications- We appreciate the acknowledgement of adjuvant medications for neuropathic pain, which providers caring for those with serious illness often use. These medications must be used carefully but, when done in that manner, can be effective.

Patient-centered prescribing- As per above, we agree with the need to take a case by case approach and especially appreciated the section on pg. 76 that notes, "*In some clinical contexts (e.g., serious illness in a patient with poor prognosis for return to previous level of function, contraindications to other therapies, and clinician and patient agreement that the overriding goal is patient comfort), opioids might be appropriate regardless of previous therapies used…Clinicians should ask patients about their preferences for continuing opioids, given their effects on pain and function relative to any adverse effects experienced*". This is exactly the approach to pain management, and treatment in general, that C-TAC advocates for on behalf of those with serious illness.

MME Dose limits- In the section on dosage on pg. 96 we appreciate this caveat, "*The recommendations related to opioid dosages are not intended to be used as an inflexible, rigid standard of care; rather, they are intended to be guideposts to help inform clinician-patient decision making. Further, these recommendations apply specifically to starting opioids or to increasing opioid dosages, and a different set of benefits and risks applies to reducing opioid dosages*".

That said, we are concerned that the guidelines discourage providers from prescribing more than 50mg MME, which is not a data-based limit and could still cause problems for those with serious illness needing higher doses. Some cancer survivors, for instance, continue to have chronic pain and may need opioid doses higher than 50 MME[vii].

Also, the advice on pg. 96 to "*use caution and increase dosage by the smallest practical amount*" is contrary to management of pain crises which calls for rapid and aggressive escalation to get the pain more quickly under control[viii].

Please consider removing/revising these points in the final guidelines.

Discontinuing opioids- We very much appreciate that the new guidelines clearly layout the risks of abrupt discontinuation or tapering, another tragic aspect of the consequences of the previous guidelines. The language on pg. 105 is appropriately strong, "*Unless there is a life-threatening issue, such as imminent overdose, the benefits of rapidly tapering or abruptly discontinuing opioids are unlikely to outweigh the significant risks of these practices… clinicians have a responsibility to provide or arrange for coordinated management of patients' pain and opioid-related challenges. Clinicians should not abandon patients. Payers and health systems should not use this clinical practice guideline to set rigid standards related to dose or duration of opioid therapy, should ensure that policies based on cautionary dosage thresholds do not result in rapid tapers or abrupt discontinuation of opioids*"**.** We are hopeful that this will help reduce/avoid abrupt discontinuation or rapid tapering of opioid doses going forward.

However, we suggest you revise the statement on pg. 102, line 2431, "*Once the smallest available dose is reached, the interval between doses can be extended*" as this shows a misunderstanding of the pharmacokinetics of these drugs which are only effective for a set amount of time, e.g., 4 or 6 hours, and ineffective when given beyond those intervals. We recommend this be corrected in the final guidelines.

Older patients- We appreciate that this is one of the special populations the guidelines address and the section on pg. 130 is very helpful, "*functional assessment is especially important in patients aged ≥65 years to better assess impact of pain on function and independence*". We would urge those providers using these guidelines to assess and monitor function for this population as it is a key contributor to quality of life for older adults.

Monitoring toxicology – We support appropriate toxicology monitoring done in collaboration with the patient and strongly agree that "*Clinicians should not dismiss patients from care based on a toxicology test result because this could constitute patient abandonment and could have adverse consequences for patient safety, potentially including the patient obtaining opioids or other drugs from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder"*(pg. 13*9).* We have seen those with opioid use disorder be treated very badly by providers and health systems when their illness is not a moral failing but instead a chronic one that is more appropriately treated medically and with compassion.

We also suggest the guidelines be revised to address opioid contracts as these are widely used in current clinical practice although they may undermine patient trust and so need to be implemented with sensitivity[ix].

Treating opioid misuse medically- This recommendation is in line with practice among providers caring for those with serious illness who are encouraged to develop their own expertise or work with substance use experts to help patients with misuse issues get medical help for them. We also appreciate recent policy changes[x] that allow any

practitioner to certify to dispense medications such as buprenorphine without additional to those patients who could benefit from such treatment.

Equity and access issue- We strongly support that the guidelines point out the patient's context is important and that providers need to be sensitive to historic disparities in pain management and access to medical care for opioid misuse when using these medications.

Thank you for the opportunity to comment on these guidelines. If you have any questions, please contact Marian Grant, Senior Regulatory Advisor, C-TAC, at mgrant@thectac.org.

Sincerely,

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[i] https://static1.squarespace.com/static/54d50ceee4b05797b34869cf/t/6205252bfddc35678ff42b18/1644504366674/CDC-2022-0024-0002_content.pdf
[ii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8119532/pdf/40122_2021_Article_235.pdf
[iii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5866727/
[iv] https://pubmed.ncbi.nlm.nih.gov/32312407/
[v] https://www.nytimes.com/2022/03/07/opinion/opioid-crisis-pain-victims.html
[vi] https://paindoctor.com/race-inequalities-pain-management/
[vii] https://pubmed.ncbi.nlm.nih.gov/33186730/
[viii] https://jamanetwork.com/journals/jama/fullarticle/181669
[ix] https://pubmed.ncbi.nlm.nih.gov/20122120/
[x] https://www.hhs.gov/about/news/2021/04/27/hhs-releases-new-buprenorphine-practice-guidelines-expanding-access-to-treatment-for-opioid-use-disorder.html