April 11, 2022

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

Re: CDC–2022–0024 – Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

Dear Director Walensky,

The Patient Quality of Life Coalition (PQLC) welcomes the opportunity to comment on CDC's proposed 2022 Clinical Practice Guideline for Prescribing Opioids. The PQLC was established to advance the interests of patients and families facing serious illness. The coalition includes over 40 organizations dedicated to improving quality of care and quality of life for all patients from pediatrics to geriatrics, as well as supporting public policies that improve and expand access to quality palliative care and appropriate pain management. PQLC members represent patients, caregivers, health professionals, and health care systems.

Pain management is an integral part of palliative care for many patients with serious illness. Palliative care helps prevent and relieve pain by systematically screening and assessing for pain and other distressing symptoms, tailoring pharmacological and other interventions to patients' individual circumstances (including medical history and stated goals of care), and carefully monitoring and adjusting treatment regimens as needed over the course of the illness.[1]

We support some of the changes CDC has made to its Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids (referred heretofore as 'proposed 2022 Guideline') and believe the document more clearly states how patients receiving palliative care are exempt. However, we continue to have concerns about the contents and very likely misapplication of the proposed 2022 Guideline by policymakers and other stakeholders. While it is important to address the national epidemic of drug-related overdose and death, access to pain treatments – including opioids – must be preserved for patients living with serious illness who need these medications and can take them safely.

We offer the following comments regarding the impacts of the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain[2] (referred heretofore as '2016 Guideline') on palliative care patients as well as comments regarding the proposed 2022 Guideline, its application and promotion.

Experience with and Impact of 2016 Guideline

PQLC members have been concerned since 2016 that policies meant to curb alarming rates of drug overdose and death are having unintended consequences on patients with serious illness – a phenomenon the authors of the proposed 2022 Guideline acknowledge. In the introduction to the proposed 2022 Guideline, CDC states that design and implementation of new laws, regulations and policies were "not the intent of the 2016 CDC Guideline," but also touts several of these policies as resulting from the Guideline, which "might have had positive results for some patients." We encourage CDC to recognize that, despite any language they choose to include to the contrary, these Guidelines will continue to be used to create policies and rules that seriously impact patient lives. Our experience with the 2016 Guideline clearly shows this, and we do not expect that to change with a new version of the Guideline.

Our primary concern with the 2016 Guideline was that the limits for dosage, duration, etc., of opioid prescriptions would restrict access for patients with serious illness, even though the Guideline was not intended to impact these particular patients. Unfortunately, our concern was validated. Polling data showed that cancer patients and

survivors taking opioids increasingly experienced challenges at the pharmacy and with insurance coverage. Reports of being unable to get an opioid because insurance would not cover it increased 19 points between 2016 and 2019, and reports of being unable to obtain their opioid prescription from the pharmacy rose 15 points. Polling data also showed that in 2019, 48 percent of patients with cancer and 56 percent of patients with other serious illness had been told by their doctor that treatment options for their pain were limited by laws, guidelines, or insurance coverage. Twenty-one percent of cancer patients, and 11 percent of patients coping with other serious illness report that their doctor said they had been flagged in their system as a potential opioid abuser.[3] Other sources also confirm that the 2016 Guideline had a chilling effect on legitimate prescribing for pain. It was used by some to wholly deny pain care, and many other patients had their opioid medications abruptly or rapidly discontinued.[4,5,6]

These data and much anecdotal evidence show that policies drawn from the 2016 Guideline have limited access to opioids for patients receiving palliative care – even though the Guideline was never meant to apply to these patients – and that these access barriers have led to negative outcomes. CDC acknowledges this as well in its introduction.[7] While we and the patients we represent appreciate this validation, CDC must take other actions to ensure that its 2022 Guideline is not "misapplied" in these same ways – as well as taking action to ensure that policymakers at every level do not continue to misuse the previous version of the Guideline to maintain or create new policies that inappropriately restrict patient access to pain treatment.

Comments Regarding the Proposed 2022 Guideline

Summary Box: This clinical practice guideline is... [and] This clinical practice guideline is not…

On the second page of the proposed 2022 Guideline, CDC includes a text box highlighting how the Guideline is intended to be used and which providers and patients it applies to. It also includes clear language about how the guideline is NOT to be used, and what patient types are exempt – which includes patients receiving the following types of pain treatment: sickle cell disease-related pain; cancer pain; palliative care; or end-of-life care.

PQLC supports the exemption of patients receiving palliative care, and its placement of prominence in the proposed 2022 Guideline. We suggest that CDC make one small change to the language in this box (and wherever it is repeated elsewhere in the Guideline). PQLC recommends CDC delete the word 'pain' from the following sentence, as shown: "…patients receiving the following types of ~~pain~~ treatment: sickle cell disease-related pain; cancer pain; palliative care; or end-of-life care." This edit makes the language more precise, since palliative and end-of-life care both involve more than pain treatment. Additionally, we strongly encourage CDC to proactively publicize the information in this box as it disseminates the new Guideline. Including this statement is not enough to ensure the 2022 Guideline is not misapplied.

Definition of palliative care

On pg. 18 of the draft 2022 Guideline, the authors state

> *This clinical practice 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 (Committee on Approaching Death: Addressing Key End of Life Issues & Institute of Medicine, 2015). Palliative care can begin early in the course of treatment for any serious illness that requires advanced management of pain or other distressing symptoms (Committee on Approaching Death: Addressing Key End of Life Issues & Institute of Medicine, 2015).*

PQLC does not object to the use of this definition, or the citation of the 2015 Institute of Medicine Report. However, we note that the CDC may want to consider using a more recent definition of palliative care, detailed in

the National Consensus Project (NCP) for Quality Palliative Care's Clinical Practice Guidelines for Quality Palliative Care.[8] These Guidelines are endorsed by over 90 national organizations. These Guidelines define palliative care as:

> *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.*

Additionally, while we recognize that the proposed 2022 Guideline is intended to apply to patients 18-years-old or older, CDC also should consider acknowledging that palliative care is appropriate for seriously ill patients of all ages, including pediatric patients.

Lastly, it is important to acknowledge that not all patients who need or qualify for palliative care are able to receive it. 2019 findings from the Center to Advance Palliative Care show that while 72% of U.S. hospitals with fifty or more beds report having a palliative care team, availability of palliative care varies widely by region and access to palliative care for people living in rural America remains limited – only 17% of rural hospitals with fifty or more beds report palliative care programs.[9] Large gaps remain in patient access to palliative care via outpatient settings.[10,11] While it is appropriate for the proposed 2022 Guideline to exempt patients receiving palliative care treatment, we want to raise CDC's awareness that this wording will exclude some seriously ill patients who *should* be receiving palliative care, but lack access to it.

References to other appropriate guidelines
On pgs. 18-19, CDC references several other guidelines that should be followed for pain treatment in patient populations who are exempt from the CDC Guideline. We recommend the CDC also cite the NCP Clinical Practice Guidelines for Quality Palliative Care, 4th edition.[12] As referenced above, these Guidelines are endorsed by over 90 national organizations and represent the standard of care for palliative care in the U.S.

Elements particularly vulnerable for misapplication
While PQLC agrees with the Guideline authors that individuals receiving palliative care should not be impacted by the recommendations, we note that some of these individuals are likely to be impacted regardless of their 'exempt' status. Our survey data show that this was the exact case after the 2016 Guideline. The proposed 2022 Guideline authors include an accurate summary of how the document was misapplied: "includes extension of the 2016 Guideline to patient populations not covered in the 2016 Guideline (e.g., cancer and palliative care), opioid tapers and abrupt discontinuation without collaboration with patients, rigid application of opioid dosage thresholds…duration limits by insurers and by pharmacies, and patient dismissal and abandonment."[13] While we support the more explicit language in the proposed 2022 Guideline that discourages the misapplication of its recommendations, we remain concerned that this problem will continue. We encourage CDC to continue to consider very carefully what it includes in its Guideline, as the likelihood for misapplication – and therefore restrictions and negative outcomes in necessary medical treatment – is high.

While the proposed 2022 Guideline does not explicitly list a maximum dosage limit for opioid pain treatment, we note that 50 MME is mentioned several times in such a way that it could be inferred as the new maximum limit. For example, see pg. 96: "Many patients do not experience benefit in pain or function from increasing opioid dosages to ≥50 MME/day but are exposed to progressive increases in risk as dosage increases" and "Additional dosage increases beyond 50 MME/day are progressively more likely to yield diminishing returns in benefits relative to risks to patients as dosage increases further." While the recommendations go on to say that "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," PQLC remains concerned that policymakers, insurance companies, pharmacy benefit managers or pharmacies will use this as an excuse to restrict opioid dosages to 50 MME in all patients, regardless of whether the Guideline is intended to apply to that patient. We are also concerned that, like with the 2016 Guideline, we will see a 'chilling effect' on all opioid prescribing above the limit suggested in the Guideline (even when prescribing over 50 MME is warranted), because clinicians will not want to be flagged as over-prescribers. We therefore strongly encourage 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. We also strongly encourage CDC to monitor for inappropriate application of the Guideline and proactively work to combat this outcome, including working with state and federal agencies and stakeholders to ensure that clinicians who prescribe higher doses of opioids when medically appropriate do not get penalized for doing so.

Promotion and dissemination of 2022 Guideline

On pgs. 164-165, CDC details its promotion efforts of the 2016 Guideline, and states that it will "update existing resources to align with the new clinical practice guideline and develop new tools and resources for clinicians, health systems, patients, and others on the use of opioid and non-opioid pain treatments — including resources supporting health equity."

It is crucial that CDC recognize its important role in promoting the 2022 Guideline when it is finalized, and PQLC supports these efforts. We urge the agency to take this task seriously. CDC should ensure that any webpage or publication under its control that contains content from the 2016 Guideline contains clear notations that the 2016 Guideline is outdated, and link to the 2022 Guideline. CDC should proactively reach out to stakeholders to suggest they do the same on any websites or in publications that reference the 2016 Guideline. CDC must ensure that clinicians, insurers/payers and pharmacies are not only aware of the new 2022 Guideline but understand how it has changed from the 2016 Guideline. CDC should be clear in communicating who is exempt from the Guideline and how the Guideline should NOT be used.

To educate clinicians on these topics, we recommend CDC conduct outreach to organizations providing and requiring continuing education to all clinician types. CDC should push these stakeholders to remove, rescind, and/or re-write any policies, guidance or other documents that use information from the previous Guideline – particularly policies that include dosage or duration limits. Lastly, we strongly urge CDC to track the effects of the 2022 Guideline on providers and patients – including on providers and patients for whom the Guideline is not intended to apply. This should include published quantitative and qualitative research, so that CDC and all interested parties can monitor the effects of the Guideline and continue to make course corrections in the future.

Our coalition members stand ready to help disseminate information about the new 2022 Guideline to palliative care clinicians and other stakeholders. We would be happy to discuss this more with CDC.

Thank you for considering our comments regarding the Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids. If you have any questions, please feel free to contact Jennifer Hoque, Associate Principal for Access to Care Policy, American Cancer Society Cancer Action Network at 202-839-3531 or Jennifer.Hoque@cancer.org.

American Academy of Hospice and Palliative Medicine
American Cancer Society Cancer Action Network
Association of Pediatric Hematology/Oncology Nurses
Cancer Support Community
Center to Advance Palliative Care
GO2 Foundation for Lung Cancer
Hospice and Palliative Nurses Association
National Coalition for Hospice and Palliative Care
National Hospice and Palliative Care Organization and Hospice Action Network
Oncology Nursing Society
Pediatric Palliative Care Coalition
Physician Assistants in Hospice and Palliative Medicine
ResolutionCare, a Vynca Health company

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[1] Morrison LJ, and Morrison RS. Palliative care and pain management. *Med Clin N Am.* 2006; 90(5):983-1004. doi: 10.1016/j.mcna.2006.05.016. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/16962853

[2] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

[3] Source for all data in this paragraph: Public Opinion Strategies, for American Cancer Society Cancer Action Network and Patient Quality of Life Coalition. Key Findings Summary: Opioid Access Research Project. June 2018. https://www.fightcancer.org/sites/default/files/ACS%20CAN%20PQLC%20Opioid%20Research%20Project%20Key%20Findings%20Summary%20Memo%20FINAL.pdf

[4] Health Professionals for Patients in Pain (HP3), led by Alford DP. Professionals Call on the CDC to Address Misapplication of its Guideline on Opioids for Chronic Pain through Public Clarification and Impact Evaluation. March 6, 2019. See https://healthprofessionalsforpatientsinpain.org/the-letter-1.

[5] Rich RLC Jr. Prescribing Opioids for Chronic Pain: Unintended Consequences of the 2016 CDC Guideline. Am Fam Physician. 2020 Apr 15;101(8):458-459. PMID: 32293841.

[6] Carlson RW, et al. Letter to Deborah Dowell, Chief Medical Officer, Opioid Response Coordinating Unit, CDC National Center for Injury Prevention and Control. February 13, 2019. See https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-NCCN-ASCO-ASH-Letter-CDC.pdf.

[7] See pg. 12 of CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022, available at: https://www.federalregister.gov/documents/2022/02/10/2022-02802/proposed-2022-cdc-clinical-practice-guideline-for-prescribing-opioids

[8] National Consensus Project for Quality Palliative Care. Clinical Practice Guidelines for Quality Palliative Care, 4th Edition. 2018. https://www.nationalcoalitionhpc.org/ncp/

[9] Center to Advance Palliative Care. America's Care of Serious Illness: 2019 STATE-BY-STATE REPORT CARD ON ACCESS TO PALLIATIVE CARE IN OUR NATION'S HOSPITALS. https://reportcard.capc.org/

[10] Hawley P. Barriers to Access to Palliative Care. Palliat Care. 2017;10:1178224216688887. Published 2017 Feb 20. doi:10.1177/1178224216688887

[11] Finlay E, Rabow MW, Buss MK. Filling the Gap: Creating an Outpatient Palliative Care Program in Your Institution. American Society of Clinical Oncology Educational Book. 2018;(38):111-121. doi:10.1200/EDBK_200775

[12] National Consensus Project for Quality Palliative Care. Clinical Practice Guidelines for Quality Palliative Care, 4th edition. Richmond, VA: National Coalition for Hospice and Palliative Care; 2018. https://www.nationalcoalitionhpc.org/ncp.

[13] See pg. 12 of CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022, available at: https://www.federalregister.gov/documents/2022/02/10/2022-02802/proposed-2022-cdc-clinical-practice-guideline-for-prescribing-opioids