

April 1, 2019

Vanila M. Singh, M.D., MACM  
Chief Medical Officer  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201



Re: HHS-OS-2018-0027

Dear Dr. Singh:

The Patient Quality of Life Coalition (PQLC) welcomes the opportunity to offer comments regarding the Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations; published on January 3, 2019. 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 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.<sup>1</sup> Palliative care is an important example of the type of care detailed in this draft report: it is balanced, individualized, patient-centric, multi-disciplinary and multi-modal.

We support the work of the Pain Management Best Practices Inter-Agency Task Force (Task Force), and many of the recommendations in the draft report. We particularly appreciate the introductory statement establishing a framework focusing on balanced pain management as a biopsychosocial model of care; individualized, patient-centered care; and a multidisciplinary approach to pain management that includes medications and other treatments. We are hopeful that this framework will support the development of additional policies that can accomplish two goals: 1) address the opioid epidemic; and 2) preserve access for patients living with serious illness who need these medications. PQLC is concerned that recent policies attempting to accomplish the first goal are having unintended consequences on accomplishing the second goal – a phenomenon acknowledged in this draft report.

Specifically, our polling data show that cancer patients and survivors taking opioids are increasingly experiencing challenges at the pharmacy and with insurance coverage – reports of being unable to get an opioid because insurance would not cover it are up 19 points since 2016, and reports of being unable to obtain their opioid prescription from the pharmacy are up 15 points.<sup>2</sup> Our polling data also show that 48 percent of patients with cancer and 56 percent of patients with other serious illness have been told by their doctor that treatment options for their pain were limited by laws, guidelines, or insurance coverage. 21 percent of cancer patients, and 11 percent of patients coping with other serious illness report having been flagged in a system as a potential opioid abuser. Therefore, we would like to build on the Task Force's work by offering the following specific comments:

**Overall Comment: Report Should be More Inclusive of All Providers** – Primary care physicians (PCPs) are an important part of pain management, but they are not the only providers delivering this care. Other physician specialties also very commonly treat pain, including oncologists and palliative care as well as other specialist-

level physicians. Therefore, we ask the Task Force to use language that reflects this reality, particularly by adding “palliative care clinicians” in instances where the draft report discusses referring patients to “specialists” or “pain specialists.” In addition to physicians, other advanced practice clinicians such as advanced practice registered nurses, physician assistants and other health care professionals are integral to pain management and/or treatment – in fact, advanced practice providers are often the main providers of this care. In addition to providers already mentioned, social workers, mental health providers, and spiritual leaders are also integral members of many palliative care teams that support best practice pain management. We urge the Task Force to be more inclusive of interprofessional providers in its final report.

**2.2 Medication, Gap 2, Recommendation 2a** – For many patients receiving palliative care, opioids are the first-line treatment for their pain because of its severity, source, or because of the patient’s comorbidities. Opioids are also important in treating other symptoms of serious illness, like dyspnea (shortness of breath), which occurs in over 50 percent of patients with underlying serious illness. Opioids are widely accepted as the first line treatment of dyspnea after other disease-targeting or modifying therapies are optimized.<sup>3,4</sup> PQLC is concerned that this recommendation does not take into account patients for whom first-line opioid treatment are clinically indicated – on its own or as part of multi-modality therapies. We recommend inserting the following underlined text in this recommendation: “...should be used as first-line therapy whenever clinically appropriate and possible in the in-patient and out-patient settings.”

**Recommendation 2b** – PQLC supports this recommendation, and notes that several evidence-informed clinical guidelines for patients with serious illness recommend treatment with opioids, relevant to our proposed edit to recommendation 2a above.<sup>5</sup>

**Recommendation 2d** – For the same reasoning discussed under recommendation 2a, PQLC recommends inserting “When clinically appropriate” to this recommendation as follows: “When clinically appropriate, opioid therapy should be initiated only with ongoing nonopioid treatments when the benefits outweigh the risks...”

**3.3.4 Research, Gap 1, Recommendation 1a & Gap 4, Recommendation 4a** – PQLC strongly supports these recommendations, as there are still large gaps in research regarding pain and how to treat and manage it. For example, research has progressed on the sensory component of pain, but much less is known about the individuality of pain perception and the brain circuitry involved.<sup>6</sup> Research progress in this area could lead to more opioid sparing/opioid avoiding pain management regimens. Increasing research investment according to these recommendations is crucial to addressing the opioid crisis and improving the quality of life for the patients our organizations represent. Research that finds new treatments for pain or better methods for using existing pain treatments will help patients with serious illness better maintain their quality of life while dealing with debilitating symptoms like pain. It will also give healthcare professionals more options in treating their patients and will reduce reliance on pain treatment with opioids.

**4. Review of the CDC Guideline** – PQLC is strongly supportive of the Task Force’s call to update and re-examine the *CDC Guideline for Prescribing Opioids for Chronic Pain* (the CDC Guideline). We agree with the draft report that “an unintended consequence of the guideline is the forced tapering or patient abandonment that many patients with chronic pain on stable long-term doses of opioids have experienced,” and that the CDC Guideline is often mis-used as a reason to limit or not provide pain treatment. We strongly support the Task Force’s statement that “clinicians should be able to use their clinical judgement to determine opioid **dose and**

duration for their patients.” We commend the Task Force for making recommendations on how to improve the CDC Guideline and its use, and we hope the CDC will pay close attention to these recommendations.

Additionally, we remind the Task Force that other evidence-based guidelines already exist for many types of patients receiving pain management. The CDC has acknowledged that patients receiving cancer treatment, palliative care, or end-of-life care often have unique therapeutic goals and balance the risks and benefits of opioids differently, clinical practice guidelines specific to these populations should be used to guide treatment and reimbursement decisions regarding use of opioids as part of pain control in pain treatment in these cases. The Food and Drug Administration Commissioner has also acknowledged this need.<sup>7</sup>

The Task Force recommendations in this section, if followed, would go a long way in improving the CDC Guideline, its use by providers and policymakers, and patient experience; we encourage the Task Force to acknowledge here that evidence-based guidelines already exist for many patient populations, as it does in other sections of the draft report. The Task Force should make recommendations on how the CDC Guideline should acknowledge these other guidelines, and integrate their promotion and use with the CDC Guideline. Examples of such Guidelines can be found in footnote five of this letter.

American Academy of Hospice and Palliative  
Medicine  
American Association of Colleges of Nursing  
American Cancer Society Cancer Action Network  
American Society of Clinical Oncology  
Association of Pediatric Hematology/Oncology  
Nurses  
Cancer Support Community  
Center to Advance Palliative Care  
Children’s National Medical Center  
Coalition for Compassionate Care of California

ElevatingHOME and VNAA  
Hospice and Palliative Nurses Association  
Lung Cancer Alliance  
National Hospice and Palliative Care Organization  
National Patient Advocate Foundation  
Oncology Nursing Society  
Pediatric Palliative Care Coalition  
Physician Assistants in Hospice and Palliative  
Medicine  
ResolutionCare Network  
Supportive Care Coalition

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<sup>1</sup> 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>

<sup>2</sup> 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>

<sup>3</sup> Mahler DA, Selecky PA, Harrod CG, et al. American College of Chest Physicians consensus statement on the management of dyspnea patients with advanced lung or heart disease. *Chest.* 2010;137(3):674-691

<sup>4</sup> Mahler DA. Opioids for refractory dyspnea. *Expert Rev Respir Med.* 2013 Apr;7(2):123-34; quiz 135.

<sup>5</sup> See Clinical Practice Guidelines for Quality Palliative Care, 4th edition; National Consensus Project and National Coalition for Hospice and Palliative Care: Domain 2: Physical Aspects of Care; 2.1.6 a-d; 2.1.7; 2.3.2-13; 2.4.1 a-c; American Thoracic Society: Assessment and Palliative Management of Dyspnea Crisis; National Comprehensive Cancer Network Guidelines on: Adult Cancer Pain, Dyspnea, Survivorship, and Management of Chronic Pain in Survivors.

<sup>6</sup> Moehring, Francie. A Neural Ensemble in the Amygdala Makes Pain Unpleasant. Pain Research Forum. March 7, 2019.

<https://www.painresearchforum.org/news/111850-neural-ensemble-amygdala-makes-pain-unpleasant>

<sup>7</sup> Gottlieb, Scott, M.D. Remarks by Dr. Gottlieb at the NCCN-ASCO Workshop. November 8, 2018.

<https://www.fda.gov/NewsEvents/Speeches/ucm625333.htm>