NATIONAL PAIN ADVOCACY CENTER

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To members of the Minnesota Opioid Prescribing Workgroup:

We are a new alliance of scientists and clinicians, civil rights advocates and people with lived experience of pain. We came together when we saw well-intended efforts to stem opioid prescribing resulting in harms to pain patients, leaving them without access to necessary medication, and in some cases, without healthcare altogether. Our mission is to advance the health and human rights of people in pain. We envision a world in which pain is treated equitably and effectively so that all people in pain have the opportunity to live full and productive lives.

We appreciate the opportunity to provide these comments to the Minnesota Opioid Prescribing Work Group (OPWG) on the draft guideline "Tapering Opioid Analgesic Therapy." Before providing specific comments on the guideline, we offer a generalized concern. In articulating this concern and the comments which follow, we second the statement prepared by the National Council on Independent Living (NCIL).

We applaud the proposed Minnesota tapering guideline for stating that: "[p]roviders should not taper a patient for their own convenience or solely to comply with system or state policy." Yet given oversight in the current policy environment, such a statement may be insufficient to deter this behavior. In this environment, it is important to consider how a guideline is likely to be applied by subsequent actors, especially in light of the cautionary example of the CDC's Prescribing Guideline for Chronic Pain, which the agency came out publicly stating has been misapplied by clinicians and policymakers.[1]

Misapplications are more likely to occur when, potentially conflicting incentives may influence clinician behavior. In Minnesota, quality measures in the Minnesota's Opioid Prescribing Improvement Program (OPIP) may undermine the good intention set forth in the tapering guideline. Specifically, the OPIP refers providers for quality improvement based on the number of their patients on long-term opioid therapy, and by the number of their patients on doses above 90 MME (morphine milligram equivalent).

Experts in pain and addiction (some of whom participated in writing the *CDC Guideline for Prescribing Opioids for Chronic Pain*) have repeatedly objected

[1] Deborah Dowell, Tamara Haegerich & Roger Chou, *No Shortcuts to Safer Opioid Prescribing*, 380 NEW ENG. J. MED. 2285,2287 (2019).

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to the use of dosage thresholds as quality measures.[2] [3] The CDC itself has stated that the dosage information in the guideline was for opioid initiation and not to set a standard for prescribing generally.[4] In order to protect patient safety, it is necessary to remove dosage thresholds from quality measures for chronic pain in the OPIP program.

In addition, it would be preferable not to rate clinicians' quality based on the number of patients on long-term opioid therapy without better contextual information about the types of conditions the clinician treats. Such a rating may also disincentivize clinicians from providing patients who rely on opioids to manage pain with care.

As the workgroup is aware, studies that have emerged over the last few years evince the importance of safeguarding patient safety in any effort to taper, given the way in which tapering is happening in practice. One study of Medicaid patients who had been on high dosages for more than 90 days found that the average time to discontinuation of opioids was 24 hours, and that it was often followed by an opioid-related hospital or emergency room visit as a result.[5] Another showed a three-fold increase of overdose death, just from destabilizing dosage.[6] Yet another showed that opioid tapering was associated with dissolution in care relationships between providers and patients.[7] And a further study found that tapering was happening too abruptly and disproportionately to women and people of color.[8]

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[2] Stefan G. Kertesz, et al. (2017) An opioid quality metric based on dose alone? 80 professionals respond to NCQA. https://medium.com/@StefanKertesz/an-opioid-quality-metric-based-on-dose-alone-80-professionals-respond-to-ncqa-6f9fbaa2338

[3] Kertesz, Stefan, MD, MSc, Ajay Manhapra, MD, and Adam J. Gordon, MD MPH FACP DFASAM CMRO, "What's Wrong With Just Counting the Patients on High Dose Opioids and Calling that Bad Care? (3 addiction docs respond to CMS)," February 9, 2018. https://medium.com/@StefanKertesz/whats-wrong-with-just-counting-the-patients-on-high-dose-opioids-and-calling-that-bad-care-3f585ceac22e

[4] Letter from CDC Director Redfield, at HP3 Health Professionals for Patients in Pain, https://healthprofessionalsforpatientsinpain.org/press-release

[5] Tami L. Mark & William Parish, *Opioid Medication Discontinuation and Risk of Adverse Opioid-Related Health Care Events*, 103 **J. SUBSTANCE ABUSE TREATMENT** 58, 60–61 (2019).

[6] Jason M. Glanz et al., *Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy*, 2 **JAMA NETW.OPEN** (2019); *see also* Jocelyn R. James et al., *Mortality after Discontinuation of Primary Care–Based Chronic Opioid Therapy for Pain: A Retrospective Cohort Study*, 34 **J. GEN. INTERNAL MED.** 2749, 2755 (2019) (increased mortality risk).

[7] Hector R. Perez et al., *Opioid Taper Is Associated with Subsequent Termination of Care: A Retrospective Cohort Study*, 35 **J. GEN. INTERNAL MED.** 36, 40 (2019), https://pubmed.ncbi.nlm.nih.gov/31428983/.

[8] Joshua J. Fenton et al., *Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-Term Opioid Therapy, 2008–2017*, 2 **JAMA NETW. OPEN** (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2755492.

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In addition, even those patients who do not face inappropriate tapers are at risk. Patients who use opioid analgesic therapy on a long-term basis are now experiencing barriers in finding clinicians willing to treat them at all. A study conducted by Quest Diagnostics and the Center for Addiction last year found that 81% of physicians are reluctant to treat a patient who uses opioids for pain,[9] and a study in JAMA found that more than 40% of primary care physicians will not accept a new patient who currently uses opioids to manage pain.[10]

It is, therefore, essential that any measures taken in tapering guidance carefully calibrate the harms and potential benefits to patients that may occur in practice. We have significant concerns about the intersection of the proposed guideline and the current quality metrics in the OPIP program.

Specific comments on "Tapering Opioid Analgesic Therapy" draft

In these specific comments, we again echo the concerns articulated by NCIL.

p. 1 In the statement on forced tapers, the phrase "immediate risk" needs clarification. Immediate risk of death due to illicit substance use is very different from immediate risk of a manageable side effect. As the CDC reaffirmed in its recent clarifications, benefit should always be weighed along with risk.

p. 2 We appreciate your recommendation to "routinely discuss the benefits and risks of continuing the current dose," replacing the previous recommendation to discuss taper every three months.

p. 3 Under #3 of the listed reasons to taper, while "demonstrated functional gain" is always a goal, this language could be amended to reflect the reality that significant functional gain may not be realistic in every case, especially because people with disabilities differ in mobility and their ability to engage in activities.

p. 4 We thank OPWG for removing "prescribed dose is greater than 50 MME per day" from the list of red flags. While dosage is one risk factor, experts acknowledge "[s]ome patients may gain important benefit at a dose of more than 90mg morphine equivalents daily." [11]

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[9] Quest Diagnostics and Center for Addiction, HealthTrends, *Drug Misuse in America: Physician Perspectives and Diagnostic Insights on the Evolving Drug Crisis* (2019) https://questdiagnostics.com/home/physicians/health-trends/trends/pdm-health-trends.html

[10] Lagisetty PA, Healy N, Garpestad C, Jannausch M, Tipirneni R, Bohnert ASB. Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids. **JAMA NETW. OPEN**, 2019;2(7):e196928.

[11] Busse J. The 2017 Canadian guideline for opioids for chronic non-cancer pain. Hamilton (ON): McMaster University; 2017. https://nationalpaincentre.mcmaster.ca/documents/Opioid_GL_for_CMAJ_01may2017.pdf

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p. 4 “Decreasing analgesic effect” may not necessarily be a red flag. Decreasing analgesic effect may also result from opioid tolerance as an expected side effect, or from a worsening medical condition. “Deteriorating quality of life not explained by medical conditions” might be a clearer choice of language.

p. 4 While bowel obstruction is a serious complication, “episodes of constipation” may be manageable and should not be considered a red flag in themselves, particularly in cases where benefits of medication include mobility and exercise.

p. 4 Available evidence does not suggest that opioids are entirely contraindicated for fibromyalgia, or for other specific pain-generating conditions. In 2019, when the Oregon Health Authority announced a proposal to limit opioid therapy for fibromyalgia, a group of experts in pain medicine opposed the proposal, noting “[i]n our own, careful review of the existing literature, we found no high-quality evidence that ties the use of opioids to specific harm in fibromyalgia patients…. Opioids are not recommended by any guideline or professional organization as a first-line treatment option for chronic pain. However, such risks are not specific to patients with fibromyalgia.”[12]

p. 5 When identifying patients who may not be good candidates for opioid taper, we recommend removing the phrase “in the near term.” There will be patients, especially those with serious conditions and disabilities, who will continue to benefit from opioid therapy over the long term as well.

p. 5 The term “inherited patients on legacy opioids” may exacerbate existing stigma against patients with chronic pain. “Inherited patients receiving prescription opioids” could be a more neutral term.

p. 5 Worth noting in the discussion of opioid use disorder: According to the DSM-5 definition, tolerance and withdrawal are not diagnostic criteria for OUD in a patient taking opioid medication as prescribed under medical supervision.

p. 6 Clinical advice in the sidebar on this page may not apply to all patients, and does not appear to be supported by federal guidance or expert consensus. The sidebar reads as follows:

> “Tell patients that their physical pain will likely get worse each time the dose is decreased, but that with time the body will adjust to the new lower dose (approximately 4 weeks), the pain level will return to baseline. The increased pain patients experience after dosage decrease does not indicate progression of their underlying

[12] Mackey, Sean MD, PhD. “Pain and Addiction Leaders Raise Alarm on Oregon Force Tapering Opioid Proposal.” https://drseanmackey.com/s/Oregon-HERC-3-7-2019ws.pdf

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> pain condition. Rather, the pain represents time-limited, opioid withdrawal-mediated pain."

According to a consensus paper by experts in pain and addiction, worsening pain with taper is not solely attributable to withdrawal, but may also be re-emerging pain from an underlying condition. "[A]void the error of assuming that all deterioration resulting from opioid reduction is due to dependence given that the processes that originally engendered the pain are likely to remain active and could be unmasked by opioid reduction."[13]

Some individuals undergoing tapering experience increased pain that does not return to baseline, does not respond to non-opioid alternative therapies, is not time-limited, and substantially limits daily life activities.

The U.S. Food & Drug Administration's safety announcement from April 9, 2019 clarifies that restoration to a previous higher dose may be necessary, for a patient who is destabilized and experiencing serious increase in pain.[14] The Oregon Health Authority's Opioid Tapering Guidelines allow for cautious dosage increase in such cases. We recommend that Minnesota DHS adopt similar language.[15]

p.8 Regarding the statement "[a]ll patients on COAT should have a multi-disciplinary
treatment plan," patients who have completed multi-disciplinary therapy programs should not be required to continue multidisciplinary therapies indefinitely. Many patients have stable medical conditions, are maximizing benefit from non-pharmacological pain management techniques, and have no further need for ongoing psychiatric or psychological treatment.

Finally, we raise one additional concern related to Minnesota tapering guidelines: the OPWG meeting slides from October 2020 suggest future revisions may involve a proposed ad-hoc advisory group on high-intensity chronic pain. OPWG plans for this committee to develop "greater consensus around the management of rare, painful conditions and relevant dosing exceptions for such conditions."

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13 Covington, Edward C. et al. "Ensuring Patient Protections When Tapering Opioids: Consensus Panel Recommendations." Mayo Clinic Proceedings, Volume 95, Issue 10, 2155 – 2171. DOI:https://doi.org/10.1016/j.mayocp.2020.04.025

14 U.S. FDA, "FDA identifies harm reported from sudden discontinuation of opioid pain medicines," 4/9/19. https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes

15 Oregon Opioid Tapering Guidelines, January 2020. https://www.oregon.gov/omb/Topics-of-Interest/Documents/Oregon-Opioid-Tapering-Guidelines.pdf at p. 14 ("A decision to return to a previous (higher) dosage during opioid tapering should be based on reassessment of the patient and shared decision making. Any upward dosage change should be made cautiously and in a step-wise fashion.")

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While we welcome consideration of especially serious and painful conditions, we caution against using a uniform approach to prescribing. According to the Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force, the therapeutic window for dosage is individualized and highly variable.[16] As the European Pain Federation notes in their draft position paper "Opioids for Chronic Non-Cancer Pain," variations in dosage may relate to pharmacogenomics and genetic polymorphism as well as medical diagnosis:

"There is wide variability in patient response to pain medications, which may be related to pain origin, pain sensitivity, cultural differences, weight, age, and prior use of opiates, as well as genetic polymorphisms. Drug-metabolizing enzymes are commonly influenced by genetic variations. The CYP450 enzymes, CYP3A4 (fentanyl) and CYP2D6 (codeine, hydrocodone, oxycodone, tramadol) are involved in the metabolism of opioids (Agarwal et al., 2017). Some patients (e.g. poor metabolizers) might require higher dosages of opioids than the ones recommended by the guidelines."[17]

The OPWG minutes from September 24 mention that randomized clinical trial results differ from the lived experience of many chronic pain patients. Although this undoubtedly reflects in part the heterogeneity of underlying conditions contained in the umbrella category we call chronic pain, it may also reflects a gap in research. If future studies were to select patients who arrive at opioid therapy as a last or late resort (and not as first-line therapy), evidence may well align with the anecdotal experience of our actual patients: that is, while opioids may not be especially effective for many or most chronic pain, they may be exceedingly effective for a subset of patients who are unresponsive to non-opioid therapies.

In the OPWG minutes from September 24, "[a] member commented that if a patient is able to maintain the lifestyle he or she desires on long-term opioid therapy that needs to be considered in any decision to change therapy." We agree with this recommendation.

We thank the Minnesota Opioid Prescribing Work Group for the opportunity to provide comments on the draft guideline "Tapering Opioid Analgesic Therapy." We thank you as well in advance for your consideration of our concerns.

If you have any questions or concerns, please do not hesitate to reach me directly at kate@katemnicholson.com or 901-409-9480.

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[16] Final Report, Pain Management Best Practices Inter-Agency Task Force: Updates, Gaps, Inconsistencies, and Recommendations, May 23, 2019, https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

[17] European Pain Federation, draft position paper "Updated position paper on the appropriate use of opioids for chronic non-cancer pain of the European Pain Federation EFIC," https://europeanpainfederation.eu/advocacy/position-papers/

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