

The National Pain Advocacy Center (NPAC), a new 501c3 organization that advocates for the health and human rights of people in pain, appreciates the opportunity to comment on the Health Evidence Review Commission (HERC) review of Guideline Note 60, from the Oregon Health Plan's Prioritized List.

NPAC is a new alliance of clinicians, civil rights advocates, and individuals with lived experience of pain. We accept no pharmaceutical or other industry funding that may create conflicts. We emphasize the importance of treating both pain and addiction, so that all can lead full and productive lives.

In the midst of the overdose crisis, we began to notice an alarming trend: well-intended efforts to stem prescribing resulted in one-size-fits-all policies that failed to protect the safety and needs of individual patients. One such effort was OHA's Guideline Note 60, which required patients with 170 back and spine conditions to replace opioid medication with non-opioid treatments.

We commend OHA for adding coverage for non-pharmacological therapies, and we hope to see these services expanded. At the same time, for some patients, opioid tapering has resulted in damage to physical and emotional health, loss of work and function, and even suicidality.<sup>1</sup> Indeed, since 2016 when OHA's Guideline Note 60 was put into place, numerous emerging studies have revealed the potential for serious harm associated with opioid dosage reduction.<sup>2 3 4 5 6 7 8</sup>

With these harms drawing nationwide concern,<sup>9</sup> we commend the Value-Based Benefits Subcommittee for the November 2020 revision of Guideline Note 60, removing references to "transitional coverage," and for specifically noting that taper is not required. These revisions will protect patient safety, in accordance with national expert consensus<sup>10</sup> and federal guidance.<sup>11 12</sup>

We recognize the lack of high quality data on efficacy of opioids for chronic pain beyond 12 weeks, although studies of most pain treatments have similar durations.<sup>13</sup> Long-term, placebo-controlled trials present practical and ethical challenges. Conversely, there is also little evidence showing that opioids lack clinical efficacy for such patients.<sup>14</sup> As the Agency for Healthcare Research and Quality (AHRQ) acknowledges, even high-quality evidence may not be fully applicable to patients with severe pain or under-studied conditions.<sup>15</sup>

Given that each treatment has no better than weak average effectiveness, with only a minority of patients deriving benefit, opioids should retain a place where other modalities have failed. As expert stakeholders wrote to OHA in 2019: "We are likewise unaware of any evidence that specifically supports opioid discontinuation for multiple conditions affecting the neck, back, or spine."<sup>16</sup>

## Recommendations:

We recommend adding a cautionary statement to Guideline Note 60, in accordance with Oregon's Opioid Tapering Guidelines. One example, from expert consensus: “[i]t is acceptable to continue higher than recommended doses of LTOT when there are neither adverse effects nor aberrant behaviors and the patient demonstrates functional and analgesic benefits.”<sup>17</sup>

Similarly, Guideline Note 60 does not specifically clarify whether dosage *increase* is a covered service. As underlying conditions change, risk/benefit balance may also change. Oregon's Opioid Tapering Guidelines allow for cautious dosage increase in such cases.<sup>18</sup>

Oregon patients who have been harmed by inappropriate taper may have medical need for dosage increase. The U.S. Food & Drug Administration (FDA) warned in April 2019 that patients who are destabilized and experiencing serious loss of function might need restoration to a higher dose.<sup>19</sup>

The November 2020 revision of Guideline Note 60 allows for long-term opioid therapy with a comprehensive treatment plan, including non-opioid therapies “if available in a patient's community and reasonably accessible to the patient.” We ask HERC to add “if clinically appropriate,” as some patients cannot benefit from further repetition of previously failed therapies. We also suggest revising the requirement to “keep active,” as patients differ in mobility and ability to engage in exercise.

At NPAC, we find patients benefit most from a combination of therapies, customized to manage risk and enable personal goals. We concur with the Oregon Medical Association's recommendation to “prescribe based on the individual history and needs of each particular patient.”<sup>20</sup>

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<sup>1</sup> Human Rights Watch. (2018) <https://www.hrw.org/report/2018/12/18/not-allowed-be-compassionate/chronic-pain-overdose-crisis-and-unintended-harms-us>

<sup>2</sup> Mark, T.L., Parish, W., Opioid Medication Discontinuation and Risk of Adverse Opioid-Related Health Care Events, 103 J. Subst. Abuse Treat. 58-63 (2019). <https://doi.org/10.1016/j.jsat.2019.05.001>

<sup>3</sup> Oliva Elizabeth M, et al. Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans. BMJ 2020; 368 :m283 <https://doi.org/10.1136/bmj.m283>

<sup>4</sup> James, J.R., et al. Mortality after discontinuation of primary care-based chronic opioid therapy for pain, J GEN INTERN MED (2019) 34: 2749. <https://doi.org/10.1007/s11606-019-05301-2>

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- <sup>6</sup> Fenton, J., et al., Trends and Rapidity of Dose Tapering among Patients Prescribed Long-Term Opioid Therapy, 2008-2017. *JAMA Netw Open*. 2019;2(11):e1916271. <https://doi.org/10.1001/jamanetworkopen.2019.16271>
- <sup>7</sup> Perez, H., et al., Opioid Taper Is Associated with Subsequent Termination of Care, *J Gen Intern Med* (Aug 19 2019). <https://doi.org/10.1007/s11606-019-05227-9>
- <sup>8</sup> Demidenko MI, et al. Suicidal ideation and suicidal self-directed violence following clinician-initiated prescription opioid discontinuation among long-term opioid users, *Gen Hosp Psychiatry*. 2017 Jul;47:29-35. doi: 10.1016/j.genhosppsych.2017.04.011. Epub 2017 Apr 27.
- <sup>9</sup> CDC Advises Against Misapplication of the *CDC Guideline for Prescribing Opioids for Chronic Pain*, April 24, 2019. <https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html>
- <sup>10</sup> Edward C. Covington, et al. Ensuring Patient Protections When Tapering Opioids: Consensus Panel Recommendations. *Mayo Clinic Proceedings*, Volume 95, Issue 10, 2020, Pages 2155-2171, ISSN 0025-6196, <https://doi.org/10.1016/j.mayocp.2020.04.025>
- <sup>11</sup> HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, October 2019. [https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage\\_Reduction\\_Discontinuation.pdf](https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf)
- <sup>12</sup> Final Report, Pain Management Best Practices Inter-Agency Task Force, May 23, 2019, <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>
- <sup>13</sup> Tayeb BO, et al. Durations of Opioid, Nonopioid Drug, and Behavioral Clinical Trials for Chronic Pain, *Pain Med Malden Mass*. 2016;17(11):2036- 2046. doi:10.1093/pm/pnw245
- <sup>14</sup> *supra* n.12
- <sup>15</sup> Chou R, et al. Opioid Treatments for Chronic Pain. Rockville, MD: Agency for Healthcare Research and Quality; April 2020. [doi.org/10.23970/AHRQEPCCER229](https://doi.org/10.23970/AHRQEPCCER229)
- <sup>16</sup> 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>
- <sup>17</sup> *supra* n. 10
- <sup>18</sup> Oregon Opioid Tapering Guidelines, January 2020. <https://www.oregon.gov/omb/Topics-of-Interest/Documents/Oregon-Opioid-Tapering-Guidelines.pdf>
- <sup>19</sup> 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>
- <sup>20</sup> <https://secureservercdn.net/198.71.233.138/b2m.8e8.myftpupload.com/wp-content/uploads/2019/11/ChronicPainTaskForceReportResponse12-5-18-Finalv1.pdf>