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March 7, 2019

To: Members of the Oregon Health Authority Health Evidence Review Commission

Re: Value-based Benefits Subcommittee: Chronic Pain Task Force Proposal and Health Evidence Review Commission Staff Suggested Revisions

Dear Members of the Health Evidence Review Commission:

We, the undersigned, write in response to the above-mentioned proposal from the Oregon Health Authority Health Evidence Review Commission (hereafter "HERC") regarding its biannual recommendations for Medicaid coverage of chronic pain treatment in Oregon.[1]

We appreciate HERC's efforts to revise its original proposal in ways that better balance the need for appropriate opioid stewardship with patient-centered care. Nevertheless, we continue to have grave concerns with the primary goal of the current proposal, namely, its call for non-consensual forced tapering off prescription opioid analgesics of a broad class of patients.

Objections to non-consensual, forced opioid tapering or dose reduction protocols

In the current proposal dated January 17, 2019, HERC endorses non-consensual forced opioid tapering protocols for a subset of patients based solely on ICD-10 diagnostic codes. The specific diagnoses include fibromyalgia and 170 conditions affecting the neck, back, and spine.

We urge HERC to reference the December 4, 2018[2] letter submitted by experts that include our signatories, which underscores that HERC's proposal contradicts all of the relevant North American guidelines for opioid prescribing. These include the:

- CDC Guideline for Prescribing Opioids for Chronic Pain[3]
- 2017 Canadian Guidelines for Chronic, Non-Cancer Pain[4]
- VA/DoD Clinical Practice Guidelines for Opioid Therapy for Chronic Pain v. 3.0[5]

Put simply, the expert bodies that developed and promulgated these guidelines declined to propose the drastic course of action that HERC endorses, that being broad non-consensual

[1] *Health Evidence Review Commission's Value-based Benefits Subcommittee Jan 17, 2019.* Oregon Health Authority, www.oregon.gov/oha/HPA/DSI-HERC/MeetingDocuments/VbBS-Materials-1-17-2019.pdf. Accessed 13 Feb 2019.

[2] Mackey, Sean MD, PhD. Oregon Chronic Pain Task Force Revised Proposal Regarding Opioids. 8 Dec 2018 https://drseanmackey.com/s/Oregon-Letter-Governor-Kate-Brown-120418-final.pdf

[3] 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. Accessed 13 Feb 2019

[4] Jason W. Busse, Samantha Craigie, David N. Juurlink. "The Canadian Guideline for Opioid Therapy and Chronic Noncancer Pain." *cmaj*, 8 May 2017, www.cmaj.ca/content/189/18/E659.

[5] VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain. Version 3.0 2017. *U.S. VA Department of Veterans Affairs*.

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tapering across certain patient populations. Forced prescription opioid tapering is also inconsistent with the Oregon Medical Board Chronic Opioid Prescribing Guidelines,[6] and the 2019 Medicare Advantage and Part D Rate Announcement and Call Letter from the Centers for Medicare & Medicaid Services.[7] Indeed, we would posit that the current proposal violates the very principles of patient-centered pain care that HERC itself declared foundational to pain treatment in Oregon.

We are concerned that HERC's broadly drawn policies for non-consensual forced opioid tapering lack evidence of benefit or safety and entail significant risks of harm. The very evidence review that HERC commissioned to inform its tapering policies uncovered *no evidence* that forced, nonconsensual opioid tapers are either safe or effective.

We are cognizant that the revisions of the January 17, 2019 proposal now permit a slower pace of taper, with the option to "pause" (though not discontinue) tapers if patients are harmed by the policy. We acknowledge the inclusion of language that references "patient-centered" tapering, yet the present proposal still demands "taper to zero" in a "unidirectional" manner, with a suggested rate of 5-10% per month for these populations.[8] Previous records and hearing transcripts from the January proposal suggest that if a tapering plan is not active, services and medications may not be covered. We must question in what way these criteria are "patient-centered," as these requirements still mandate non-consensual forced tapering, which can cause grave destabilizations to stable patients, without evidence of benefit.

While we appreciate the slower pace granted in these forced tapering scenarios, many of the harms (including death) that we have observed following forced tapers occurred in tapers that were slow, not fast. These harms, which have been documented and observed in clinical practice, include:

- Patient abandonment
- Increased use of medical resources
- Patients turning to illicit opioids
- Acute (days) and protracted (months) withdrawal symptoms
- Medical and psychological destabilization
- Increased pain, distress, suffering, and disability
- Suicidal ideations, attempts, and completions

Beyond clinical observations of harm, we are aware of at least four comprehensive studies of opioid discontinuation (outside of voluntary taper in model programs) that are in process and have reached the abstract, manuscript submission, or peer-review stage. These emerging studies,

[6] Oregon Medical Board Chronic Opioid Prescribing Guidelines
https://www.oregon.gov/omb/Topics-of-Interest/Documents/Chronic-Opioid-Prescribing-Guidelines.pdf pp.7-9 Accessed February 18, 2019

[7] 2019 Medicare Advantage and Part D Rate Announcement and Call Letter." *Centers for Medicare and Medicaid Services*. www.cms.gov/newsroom/fact-sheets/2019-medicare-advantage-and-part-d-rate-announcement-and-call-letter. Accessed 13 Feb 2019.

[8] Chronic Pain Task Force, January 17, 2019, p. 80, 82, 98

whose findings will become available within the year, are likely to alter our present understanding of the consequences of opioid stoppage in critical ways. It is thus advisable that HERC await the results of these studies before creating an unprecedented state mandate for forced opioid tapering across a broad population of patients.

It is important to note that, should HERC's proposal go forward, Oregon lacks any state-wide infrastructure that would ensure careful symptom monitoring of patients to identify and address iatrogenic patient harms caused (not by the opioids) but by the forced taper. There is no evidence that clinicians are skilled or capable at carrying out mandates to taper opioids in patient-protective ways. Indeed, suicides reported in Oregon[9] and other states suggest the opposite.

Physicians will also be affected by HERC's proposal, which will place them in the untenable position of choosing between violating the ethical tenets of their Hippocratic oath and medical licenses—to do no harm—and complying with Oregon's mandates.

Given the unsettled nature of current data, the potential for harm to patients and clinicians, and Oregon's lack of protocols to protect against such harms, we urge HERC to remove all forced opioid tapering requirements for all patient populations from consideration.

Objections to the application of forced tapering mandates to patient subgroups designated by diagnosis

We briefly address HERC's decision to select persons diagnosed with fibromyalgia or one or more of 170 specific spine, back, and neck conditions for forced opioid tapering.

According to HERC's proposal, the *[u]se of opioids should be avoided [for fibromyalgia] due to evidence of harm in this condition,"* and *"[t]here is insufficient evidence on the long-term use of opioid therapy for the treatment of fibromyalgia."*

We were able to find only a single statement in HERC's record suggesting that opioids result in unique harms in fibromyalgia patients: "*This sentence was added to the guideline based **on expert input** which indicated that opioids for fibromyalgia actually exacerbated the condition and therefore were a source of harm.*[10]*"* It is impossible to evaluate the accuracy of this statement because we do not know the identity of the expert or the basis of their opinion. In 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.

One other fibromyalgia-specific statement appears in the January 2019 "Chronic Pain Task Force Proposal for Review by VbBS[11]" with regard to tramadol: "*Kim Jones, PhD has previously testified to the CPTF regarding the possible benefits of tramadol, a type of opioid, for treatment of*

[9] Hawryluk M. Opioid crisis: Pain patients pushed to the brink. Bend Bulletin. June 2, 2017.

[10] *Id.*

[11] *Id.*

fibromyalgia. The OHA Pharmacy and Therapeutics Committee recently completed a review of tramadol for fibromyalgia and found no evidence of benefit for this medication." Again, we were unable to locate the basis for this conclusion. We are, however, aware of at least one randomized, blinded, placebo-controlled trial of 315 persons over 91 days, in which tramadol outperformed placebo for both pain relief [12] and pain-related function.[13] While a single trial of this nature would not justify designating tramadol as a first- or even second-line therapy for fibromyalgia, it raises questions about the evidentiary basis of a policy that, in regard to fibromyalgia, prohibits all opioids (including tramadol) and mandates forced opioid tapering.

We are likewise unaware of any evidence that specifically supports opioid discontinuation for multiple conditions affecting the neck, back, or spine.

Opioids do, of course, present risks of harm for any long-term pain condition, including the conditions for which HERC has retained opioid coverage, which is why 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 or conditions of the back, neck, or spine. The general lack of evidence beyond a 12-week duration on the effectiveness of opioids for long-term pain care is also not unique to fibromyalgia or conditions of the back, neck, or spine.

The guidelines generally speak to opioid *initiation* rather than *discontinuation*. For the reasons we have indicated above, significantly different considerations and risks apply to discontinuation in patients with established and long-term opioid prescription use.[14] Patients who currently rely on long-term opioid therapy will be exposed to new and potentially grave health risks by HERC's forced tapering proposal.

Concerns regarding the proposal to substitute complementary and integrative treatment for prescription opioid analgesia in patients undergoing tapering

Oregon's Chronic Pain Task Force has proposed replacing long-term opioid therapy with a limited number of non-interventional treatments.

Expanding access to integrative and complementary treatment options is helpful. Coverage of such treatments may benefit some patients in ways that could limit their need for other therapies, including long-term opioids. To achieve this end, it is important to ensure that patients in geographically diverse locations across the state have meaningful access to such therapies.

[12] Bennett RM, Kamin M, Karim R, Rosenthal N. Tramadol and acetaminophen combination tablets in the treatment of fibromyalgia pain: a double-blind, randomized, placebo-controlled study. Am J Med. 2003;114(7):537-45.

[13] Bennett RM, Schein J, Kosinski MR, Hewitt DJ, Jordan DM, Rosenthal NR. Impact of fibromyalgia pain on health-related quality of life before and after treatment with tramadol/acetaminophen. Arthritis Rheum. 2005;53(4):519-27.

[14] MacLean AJ, Schwartz TL. Tramadol for the treatment of fibromyalgia. Expert Rev Neurother2015;15(5):469-75. doi: 10.1586/14737175.2015.1034693

Embracing a policy that broadly substitutes integrative and complementary approaches for—and specifically excludes—pharmacological treatment is something altogether different, however.

Prudence dictates that the effectiveness and limitations of these treatments be considered. An exhaustive analysis conducted by the Agency for Healthcare Research Quality[15] found the quality of evidence supporting most complementary and integrated services as well as the evidence of their effectiveness to be low or moderate. Few studies reported a likelihood of a clinically significant improvement. Importantly, these studies were conducted under 'best-case scenarios' that did not include the physical and psychological duress associated with forced prescription opioid tapering.

Ongoing studies are assessing the value of complementary and integrative treatments in the context of consensual or voluntary tapering. However, we are far from being able to draw conclusions as to how any replacement treatment will impact forced opioid tapering in a large population.

Other considerations

Overdose-related deaths peaked in Oregon in 2015 (220) and have fallen by 25%. Out of 35 states with good to excellent reporting, Oregon currently has the fifth lowest rate of prescription opioid-related overdose deaths in the country. However, it is troubling that from 2016 to 2017, Oregon also saw the second highest rate of increase in deaths related to heroin and synthetic opioids[16] (e.g. illicit fentanyl) of any state, with an increase of 90%.

While the absolute rate is still comparatively low, it is concerning that Oregon saw almost a doubling of deaths in one year due to heroin and synthetic opioids. Thus, we implore Governor Brown not to conflate concerns regarding prescription opioids with the dangers of illicit opioids. It is well recognized that these are largely separate public health issues – each requiring different actions.

Conclusions

The ultimate test of policy change in health care is not whether prescription use can be reduced (as is now the case in every state), but how we can ensure safety and functioning of the people whose lives are affected.

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[15] Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review. *AHRQ.* 11 June 2018. effectivehealthcare.ahrq.gov/sites/default/files/pdf/nonpharma-chronic-pain-cer-209.pdf. Accessed Feb 15, 2018.

[16] Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017. MMWR Morb Mortal Wkly Rep 2019;67:1419–1427. DOI: http://dx.doi.org/10.15585/mmwr.mm675152e1

To summarize our findings, across all domains of assessment, HERC's proposed policy in Oregon provides:

- No evidence to support the diagnostic code selections applied;
- No evidence to support the practice of large-scale forced prescription opioid tapering;
- No evidence to assure absence of patient harms in forced prescription opioid tapering;
- No evidence for 'replacement' of established long-term opioids with behavioral and integrative approaches within the context of mandatory opioid tapering;
- No evidence to suggest patients across the state of Oregon and in rural settings will have meaningful and sustained access to covered behavioral treatments;
- No evidence that Oregon has established *and tested* accessible and meaningful prescriber and patient infrastructure to allow for careful monitoring and risk mitigation in patients who may be the subject of an opioid taper;
- No evidence to support patient safety from medical and psychological destabilization that has been reported nationally with forced opioid tapering.

This last year has seen a rising chorus of concern regarding the risks posed by forced opioid tapering among professionals in pain/addiction and the national and international media.

One example is a consensus document opposing forced prescription opioid tapering that was signed by 130 stakeholders who represent vastly different views on opioid prescribing. This document is part of the federal record of the HHS Pain Management Task Force, was published in *Pain Medicine* (Darnall et al., 2018), and has been covered by 17 media outlets on three continents, including *Reuter's Health*, the *LA Times*, the *NY Times*, *Forbes*, and *MedPage Today*.

Oregon's tapering proposals, in particular, have garnered attention. The international watchdog organization, Human Rights Watch, highlighted Oregon's forced tapering proposals in its recent report outlining human rights violations in pain care, as did the *New York Times* Opinion Page on February 9, 2019.

We fear that HERC's proposal is, in essence, a large-scale experiment on medically, psychologically, and economically vulnerable Oregonians, at a moment when Oregon has already seen a significant reduction in opioid prescribing and prescription opioid-related deaths. The evidence supports that this proposal represents an alarming step backward in the delivery of patient-centered pain care for the state of Oregon.

We thank HERC for allowing us to provide input on this matter. Your attention to our serious concerns is greatly appreciated. Because the policies set by Oregon officials are likely to reverberate across the country, they are of significant interest to people with pain, professionals, and the media.

Each signatory has expressed a willingness to work with Oregon Medicaid officials, the distinguished Task Forces, and HERC to detail their concerns more directly and provide any assistance that will help protect the health of Oregon Medicaid patients.

Sincerely,

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