

March 21, 2023

Humayun J. Chaudhry, DO, MACP
Secretary
President and CEO
Federation of State Medical Boards
400 Fuller Wiser Road
Euless, TX 76039

Re: Comments on FSMB Draft Policy: Strategies for Prescribing Opioids for the Management of Pain

Dear Dr. Chaudhry:

On behalf of the National Pain Advocacy Center (NPAC), I am writing to commend the Federation of State Medical Boards (FSMB) on its proposed draft policy, "Strategies for Prescribing Opioids for the Management of Pain" (Draft Policy) and to offer modest suggestions for amending it.

NPAC is a 501(c)(3) nonprofit alliance of clinicians, scientists, public health experts, and people with lived experience of pain, working to advance the health and human rights of people living with pain. We envision a world in which pain is treated equitably and effectively so that all people living with pain have the opportunity to live full and productive lives.

As an organization dedicated to protecting the rights of people living with pain and to ensuring equitable care, we are pleased with the careful balance reflected in this Draft Policy. We specifically commend the:

- emphasis that pain care should be individualized;
- recognition that opioids can play a role in managing pain and that no specific dose threshold is appropriate for all patients;
- focus on shared decision-making when opioids are initiated, tapered, or discontinued, and the acknowledgment of risks associated with tapering;
- emphasis on comprehensive pain management while highlighting the equity issue that the full range of pain treatments is not equally accessible to all patients.

I was grateful to be invited to speak to the FSMB on the mounting barriers to care that people who use opioids to manage pain confront today and to provide initial input on this draft. The widespread implementation of one-size-fits-all policies aimed at reducing opioid prescribing has imposed system-wide barriers on people with pain – at the pharmacy, with payers and providers, and in accessing healthcare altogether.

Meanwhile, cutting the medical supply of opioids has not improved drug-related mortality: as prescribing has dropped by nearly 50% since 2011, overdoses have doubled driven largely by illicitly-manufactured fentanyl, its analogs, and stimulants. Nor has taking medication away from people with pain made them safer: more than a dozen studies show risks with opioid discontinuation and tapering, including a three to five-fold increased risk of overdose and suicide, disruption of care relationships, and the destabilization of people's health, mental health, and lives. See Appendix A.

We appreciate the Draft Policy's responsiveness to the current policy environment and the FSMB's efforts to reconcile the continuing need for attention to the evolving addiction and overdose crises while ensuring that people with pain receive appropriate care.

Minor suggestions regarding language in Draft Policy are enumerated below. Our chief concern is that the summary points in the conclusion do not reflect the balance of the overall Draft Policy. In places, they read as red flags, are reductive, and fail to contain qualifiers that appear elsewhere in the document. On occasion, what appears in bold does not correlate with the text that follows it. Given the role summaries (or top-line recommendations) played in the misapplication of the CDC's 2016 prescribing guideline, careful attention to the summary points is critical.

Comments on the Draft Policy

Page 7, Line 16. Add at the end of the sentence: "but does not, by itself, characterize dependence syndrome."

Page 8, Lines 21-23. Asking about a history of abuse should be qualified with language that "a history of abuse should not, by itself, be a reason to deny a particular therapy." Otherwise, this recommendation raises the ethical issue of doubling down on disadvantage or doubly victimizing someone who may otherwise be a good candidate for the therapy. It may also be useful to state that the question should be asked of persons of all genders, given that the ORT historically only considered histories of abuse in women.

Page 9, Lines 16-17. A qualifier such as, "a family history of mental disorder or the presence of anxiety or depression should not, by themselves, be a reason for denying a particular therapy," is needed. When discussing the role anxiety or depression plays in pain, it may be useful to add, "These concerns speak to the importance of integrating behavioral therapies where accessible and desirable, and, where appropriate, referral to behavioral care providers."

Page 11, Line 9. Few patients with significant pain expect treatment to eliminate pain. Amend to “even when pain is *not substantially reduced or eliminated.*”

Page 12, Line 13. Amend the first bullet point to read “potential risks and benefits of initiating *and discontinuing opioid therapy*” in light of the studies on risks associated with discontinuation. Patients should be informed upfront about expectations related to opioid initiation and its discontinuation if the therapy is not effective.

Page 17, Lines 1-5. Some attention might be given to what proper discharge is – for example, it may be problematic to discharge someone currently using opioids if it forces them into withdrawal without efforts to provide continuity of care.

Page 18, Lines 4-5. Add “significant” before “failure to comply with the treatment agreement” to mitigate the risk that a single concern over a request for an early refill or something of that nature will lead to discontinuation of care.

Page 18, Lines 9-21. It would be useful to include additional studies and guidance on tapering, such as what to do if a patient fares poorly during the taper, but doing so may involve a level of specificity that the drafters wish to avoid.

Finally, while person-centered care encourages engaging family members in treatment plans, this Draft Policy needs to underscore that the involvement of family members requires the consent of the patient.

Comments on the Conclusion

The conclusion should be redrafted to reflect the tone and balance of the Draft Policy. Suggestions for re-organization and redrafting follow. Edits are underscored and italicized for clarity. The bolded text reflects topics bolded in the Draft Policy.

- 1) Begin with the summary point on individualization, a philosophy embraced throughout the Draft Policy:

Emphasis should be placed on individualized decision-making: The decision to initiate, continue, taper, or discontinue opioid therapy is one that must be made on an individualized basis. There is no specific numeric threshold or single indicator that applies equally to all patients. Patients with pain deserve the same care and compassion as any other patient with complex medical conditions.

- 2) The summary point about assessment (as amended) flows well next:

Adequate attention to initial assessment to determine if opioids are clinically indicated and to determine benefits and risks associated with

their use in a particular individual with pain: Not unlike many drugs used in medicine today, there are significant *potential* risks associated with opioids, and therefore benefits must outweigh the risks.

Explanation: This is a risk, benefit calculus as the rest of the document makes clear. Both should be emphasized. “Potential” is added because it is the qualifier used elsewhere in the Draft Policy.

- 3) The summary point about education and informed consent with suggested amendments might follow:

Adequate attention to *shared decision-making*, patient education, and informed consent: The decision to begin opioid therapy is a shared decision of the clinician and patient after a discussion of the potential benefits and risks and a clear understanding *of why opioids are being considered for the patient*, that the *evidence* basis for the use of these medications for chronic pain is limited, that *sometimes* pain may worsen with opioids, and *that* taking opioids with other substances (such as benzodiazepines, alcohol, cannabis, or other central nervous system depressants) or certain conditions (e.g., sleep apnea, mental illness, pre-existing substance use disorder) may increase the risk for adverse events [*delete as redundant: and harms*].

Explanation: If the drafters wish to reference alternative treatments, language such as, “Providers should optimize the use of alternative treatments where accessible, available, and appropriate,” could begin the summary point. Alternatively, this point could be its own bulleted summary. Stating this in the affirmative is far less stigmatizing than a directive to avoid reliance on opioids or opioids at higher doses.

- 4) The next summary point (as amended) could address the titration of the dose:

When opioids are initiated, they should be given at the lowest dose appropriate for the individual patient, considering the patient’s condition, needs, and preferences and keeping in mind that risks may increase with dose, as well as in the setting of other comorbidities (i.e. mental illness, respiratory disorders, pre-existing substance use disorder, and sleep apnea) or with concurrent use with respiratory depressants such as benzodiazepines or alcohol. **Dosage considerations should be individualized and no preset dose threshold should be applied to all patients.**

Explanation: For balance, there should be some language about the potential benefits as well as risks. The suggested addition at the end reflects language in the body of the Draft Policy and is important to mitigate harm from policies that implement preset dose thresholds.

- 5) As currently drafted, the summary point on monitoring is less about monitoring than about what to do if things don’t go well. What follows consolidates monitoring with risk management:

It is strongly recommended that prescribers be prepared for risk management when opioids are prescribed.

- Risk management includes the utilization of available tools for risk mitigation such as checking prescription drug monitoring programs (PDMPs) in advance of prescribing opioids and in an ongoing manner while monitoring the patient to assess for benefits and mitigation of harm.
- Continue opioid therapy if clear and objective outcomes are being met.
- If beneficial outcomes are not met or harm is observed, some patients may benefit from opioid dose reductions or weaning off the opioid. However, tapering or discontinuation carry significant risks and should be done with shared decision-making and input from the patient.

Thank you again for the ongoing opportunity to have input on this Draft Policy. If it is adopted in May, we encourage the FSMB to urge members to rescind one-size-fits-all policies where they exist and replace them with policies concordant with this policy.

Sincerely,

Kate M. Nicholson

APPENDIX A

On Barriers to Care:

- Two surveys found [more than 40% of primary care clinicians are unwilling to take on a new patient who uses opioids](#) to manage pain.
- The original study is of clinics in [Michigan](#) (Lagisetty, JAMA Netw Open 2019).
- A follow-up study looked at [primary care clinics in 9 states](#) (Lagisetty, PAIN 2021).

On Risks Associated with Opioid Discontinuation and Tapering:

- Just changing a patient's dose resulted in [a three-fold increased risk of overdose death](#). (Glanz, JAMA Netw. Open 2019).
- In Medicaid patients on opioids for more than 90 days, discontinuation often happened abruptly (within 24 hours) with [almost half of such cases resulting in hospitalization or an ER visit](#) (Mark, J Subst Abuse Treat. 2019).
- Tapering resulted in an [increased risk of death](#) in primary care settings (James, J Gen Intern Med 2019).
- Veterans who were tapered [experienced a higher risk of death](#) from overdose or suicide (Oliva, BMJ 2020).
- Opioid tapering was [associated with later termination of care](#) relationships (Perez, J Gen Intern Med 2020).
- Discontinuation of opioids in stable patients [is on the rise](#) and often happens abruptly (Neprash, J Gen Intern Med 2021).
- Dose tapering is associated with [mental health crises and overdose events](#). (Agnoli, JAMA 2021).
- Heightened [incidence of overdose and mental health crisis continued two years post-taper](#). (Fenton, JAMA Netw. Open 2022).
- [Heightened risk of overdose and suicide](#) occurred in patients without OUD/misuse risk with no difference in outcome in abrupt vs. slow tapers. (Larochelle, JAMA Netw. Open 2022).
- [Increase in emergency department visits and hospitalizations, fewer primary care visits](#), and lower medication adherence was associated with tapering (diabetes, hypertension). (Magnan, JAMA Netw. Open 2023).

On Reduced Risks with Voluntary Tapering:

- The largest study of [voluntary tapering shows that where there is patient buy-in, education, and readiness to taper, and when the taper is not unidirectional, most patients reduced their dose](#). (Darnall, JAMA Intern Med. May 2018).



Kate M. Nicholson, JD
Executive Director and Founder
kate@nationalpain.org
(800) 735-0818

P.O. Box 4172
Boulder, CO 80302

info@nationalpain.org
(303) 909-3175