AMA
AMERICAN MEDICAL ASSOCIATION

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President/CEO
Federation of State Medical Boards
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Dear Dr. Chaudhry:

On behalf of the physician and medical student members of the American Medical Association (AMA), I want to thank you for your leadership and efforts by the Federation of State Medical Boards (FSMB) to provide updated policy intended to reduce opioid-related morbidity and mortality, while preserving access to opioid-based therapy for patients who must rely, at least in part, on this approach to manage their pain. The AMA appreciates the opportunity to participate in the workgroup formed by FSMB to update the 2013 FSMB model policy on the use of opioid analgesics in the treatment of chronic pain. The 2017 model policy update contains important revisions and clarifications to help support physicians' clinical decision making while avoiding a one-size-fits-all mandate. Every patient presents a unique set of circumstances, and the FSMB's revised model policy demonstrates respect for physician autonomy, while also providing guidance and serving as a resource for physicians and state medical boards.

We do, however, have several comments for your consideration to help further clarify the new model policy so that it will be a more balanced and helpful resource for physicians and state medical boards. Our comments below are grouped according to order in which they appear in the model policy: Preamble; Focus of Guidelines; Definitions; FSMB Guidelines; and Conclusion.

<u>Preamble</u>

This section's emphasis on an expectation that physicians must understand the totality of pharmacologic and non-pharmacologic strategies for pain management is important, but must remain aspirational. While the AMA strongly agrees that physicians must ensure that they have the necessary education and training to determine a course of treatment for chronic pain, a vast difference exists in the training and clinical experience among recent graduates, residents, young physicians and physicians who have been in practice for many years. The AMA recommends, therefore, that FSMB include a sentence beginning on line 37: "[t]his education and training typically begins in medical school and residency, and continues throughout a physician's professional career."

Focus of Guidelines

The AMA agrees that the "[g]uidelines do not operate to create a specific standard of care," and we further agree that the model policy encourages physicians to consider non-opioid and non-pharmacologic modalities. We note, however, that patients may have difficulty accessing non-pharmacologic modalities due to limitations in insurance coverage or lack of access to multidisciplinary sources of care. The AMA stands ready to work with FSMB to call further attention to these limitations and urge health insurance companies and public payers to ensure access to non-pharmacologic therapies so that physicians and patients have all options available to care for a patient's pain.

Definitions

The AMA appreciates the attention that FSMB has given to this section and its reliance on diagnostic standards such as the DSM-V™ to ensure that the model policy is based on the highest level of clinical evidence. With that perspective, we recommend that where claims are made in this section, FSMB provide specific citations to ensure that state medical boards, physician organizations and others understand the basis for the recommendation and have the opportunity to garner additional information, if needed. One claim, in particular, is related to the definition of "Tolerance," which states that "[t]olerance is common in opioid treatment, [and] has been demonstrated following a single dose of opioids." Given the implications of this statement on clinical practice and the potential for states to rely on the model policy in legislative and regulatory actions, we strongly urge FSMB to provide the medical evidence and clinical relevance for this claim in humans, or remove the claim until such time that the evidence can be provided.

FSMB Guidelines

We first want to highlight the importance of FSMB's focus on treatment for the individual patient. The national discussion about opioid-related morbidity and mortality all too often reduces the approach to the need to restrict the use of opioid analgesics without reciprocal consideration of how this impacts patients who must rely on opioids. The AMA agrees with the need to consider all clinical strategies for pain care, and only to initiate opioid therapy if the benefits are likely to outweigh the risks. The FSMB's extended discussion on the need for careful assessment and evaluation on a patient-specific basis will help physicians understand what can be helpful in evaluating patients without dictating specific treatments that must be used. Given that focus, our comments on this section are intended to seek further clarification.

- Line 344 calls for patients to give his or her physician "permission to query the state's Prescription Drug Monitoring Program (PDMP)" as part of a treatment agreement. Typically, a patient will not be required to do this, or the physician will be required to check as a matter of state law. The AMA recommends that this phrase be deleted and in its place, add "discuss with the patient how and when the PDMP will be reviewed as part of the patient's care."

- Line 362 suggests that the patient be educated that complete pain relief "is not to be expected." We suggest framing this discussion in a more positive manner by using the phrase "is a goal, but may not be fully achievable."

- Line 374 suggests that FSMB is recommending a pharmacy "lock-in" requirement for patients with chronic pain. While this may be part of some treatment agreements, it may not be appropriate or realistic in some situations.

- Lines 404-407 claim that concurrent use of opioids and benzodiazepines "greatly increases the risk of adverse events including addiction and death." While we are certainly aware of the latter, we urge the FSMB to provide the citation for the former. If no such citation is available, we recommend deleting the claim that concurrent use of opioids and benzodiazepines increases the risk of "addiction." This is also important due to the FSMB's careful discussion about the difference between addiction and dependence.

- Line 410 – we note that the Centers for Disease Control and Prevention has not set any specific dosing guideline so much as it has recommended different dosing and quantity thresholds. We urge FSMB to clarify the language accordingly.

- Line 460 – we recommend removing the term "chromatography" and replacing it with "confirmatory testing" to account for the broader range of tests available.

- Lines 513-514 – we suggest that "intervention" may not be the most medically accurate term. Rather, we recommend FSMB consider "evaluate" or a similar clinical indication. Similarly, we recommend adding "change in pain intensity" as one of the factors that may be the cause of the misuse.

- Line 561 – the term "end point" might be better explained by "exit strategy" or "tapering strategy" or another term(s) that identify a need to change course rather than abruptly "end" the patient's care.

- Lines 567-568 – while we agree that "functional improvement" may be one indication of effective treatment and benefit to the patient, it is also possible that "stability" would be a benefit indicating the need to continue a patient's current therapy.

Conclusion [in the model policy]

We have several concerns with this section, including that it appears to introduce new concepts not discussed in the main body of the model policy. For example, line 634 introduces the term "potentially abusable medications" when the context appears to suggest "controlled substances," which are scheduled according to their potential for abuse. Also, line 635 introduces "chemical coping," but the term or the clinical science surrounding the term is not defined or discussed elsewhere. If FSMB intends to keep this term, we recommend defining it. On line 657, we recommend that FSMB use Food and Drug Administration labeling information to indicate when opioid therapy should be considered, that is: "when alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain." Finally, to bolster the concept of multimodal care, we recommend adding language noting the potential for a variety of screening and evaluation tools – in addition to a PDMP – that could help a physician's decision-making process.

In sum, the AMA has worked with federal and state policymakers to address opioid-related morbidity and mortality for many years. We remain committed to continuing our collaboration with the FSMB and other stakeholders to implement effective solutions to reverse this epidemic. Physicians work hard to balance their ethical obligation to treat patients with pain management needs with the need to help prevent opioid misuse, overdose and death. Physicians must confront numerous challenges in their efforts to maintain that balance. The revised FSMB model policy takes important steps toward restoring the necessary balance. We urge you to consider our recommendations to help make the model policy more clear and impactful.

If you have any questions regarding the recommendations and comments in this letter, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, Advocacy Resource Center, at daniel.blaney-koen@ama-assn.org or (312) 464-4954.

Sincerely,

James L. Madara, MD

cc: Patrice A. Harris, MD, MA