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Lisa Robin
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Federation of State Medical Boards
1300 Connecticut Avenue, NW
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Washington, DC 20036

Re: American Medical Association comments regarding FSMB Model Pain Policy

Dear Ms. Robin:

The American Medical Association (AMA) greatly appreciates the opportunity to provide comments regarding the Federation of State Medical Boards (FSMB) Model Pain Policy (Draft Policy). As the first significant revision to the FSMB's 2004 Model Policy, the AMA believes that the FSMB's work represents an important opportunity to update this policy, help guide the nation's medical boards on this critical issue and assist in creating a clinical practice environment that is conducive to managing pain while avoiding diversion and substance misuse. A balanced approach recognizes that both under-treatment of pain in the United States (including pain among patients with chronic conditions and those who are critically ill or near death) and prescription drug abuse are serious public health problems that have intensified in recent years.

In your April 23, 2013 email, you asked for our comments to focus on four distinct areas. We organized our responses accordingly.

1. Does the statement provide adequate guidance to practitioners?

Generally, the AMA believes that the nation's challenges in combating prescription drug abuse and diversion must be focused on public health solutions that promote physician education and public awareness. This includes balancing a physician's ethical obligation to treat patients with legitimate pain management needs against the need to identify drug seekers and prevent abuse, overdose and death from prescription drugs. A critical component in this includes appropriate guidance from state medical boards to help physicians navigate standards of care and the realities of individual patient needs with evolving medical research where available. There is no question that the Draft Policy seeks to provide guidance to physicians.

On one hand, the AMA observes that there are more than 40 separate instances in the Draft Policy of what Boards "expect" and what physicians "should" do with respect to patient evaluation, treatment and monitoring. This raises the question of whether the FSMB intends for all of these to function as a new standard of care. While some of these may be reasonable (e.g., "the medical record should

document the presence of one or more recognized medical indications for prescribing an opioid analgesic”), there also are multiple references to different assessment and screening tools, informed consent and treatment agreements and patient questionnaires.

While the AMA agrees that the various tools and resources the Draft Policy recommends may be useful in some circumstances, we ask that you consider the following questions. Does the FSMB intend that all physicians use all of the tools for all patients who are prescribed controlled substances for chronic pain? Are these tools part of what the FSMB considers a “safe and appropriate standard of care,” and if not used, a “departure from accepted standards of practice?” In addition, does the FSMB intend for state medical boards to provide these tools to physicians, as well as providing the resources and education necessary to properly integrate these tools into daily practice?

In addition to the potential confusion about the tools physicians “should” employ in caring for patients with chronic pain, the AMA is concerned about the Draft Policy recommendations for patients with a history of substance use disorder. The population with these problems is very heterogeneous. While we agree that these patients demand a higher level of attention, the Draft Policy’s hard line against providing treatment to a patient with an active substance use disorder “until they are established in a treatment/recovery program,” may not take into account the lack of access to treatment/recovery programs and addiction specialists.

Alternative language related to this patient population might acknowledge the following: (1) such patients require careful structuring and monitoring of care, and co-management by an addiction professional should be considered; (2) a patient with a well-established recovery who is still “working” a program and has strong social support might be considered a candidate for a trial of an opioid; (3) patients with an active addiction usually present such concerns about adherence and unexpected toxicity that opioid therapy is not appropriate; and (4) patients who, despite care in structuring and monitoring opioid therapy, are unable to use opioids safely, but who require them for effective treatment of pain, may need to receive opioids using an addiction paradigm of care, either through a methadone maintenance clinic or through a Suboxone™ provider.

In summary, the AMA recommends that the FSMB carefully review each instance where the Draft Policy uses “should,” “must,” “expects” and similar phrases and consider whether each additional requirement placed on physicians is appropriately balanced with the realities of medical practice, resources and the need to appropriately treat and manage patients’ pain.

2. Does the statement afford sufficient latitude to State Medical Boards in executing their responsibilities?

As noted above, the Draft Policy contains several dozen new requirements for state medical boards to use in evaluating physicians’ medical judgments and treatment decisions. In reviewing a comparison of comparable sections of the FSMB’s 2004 Model Policy and 2013 Draft Policy on the Use of Opioids in the Treatment of Chronic Pain, the AMA observes that there are many areas of the Draft Policy that are completely new, greatly expanded or thoroughly revised. These new mandates, therefore, may not provide much latitude to state medical boards in their interpretation of the Draft Policy, if adopted in total.

Furthermore, there are several statements in the Introduction and Draft Policy itself that may present state medical boards with conflicting messages. For example, the AMA is pleased that the FSMB clearly recognizes the need “to encourage the legitimate use of opioid analgesics for the treatment of pain while emphasizing the need to safeguard against their misuse and diversion.” Similarly, the AMA agrees with the FSMB’s goal of “emphasiz[ing] the professional and ethical responsibility of physicians to appropriately assess and manage patients’ pain while monitoring and intervening for aberrant or unsafe medication-related behaviors.” The FSMB’s further discussion of the complicated nature of pain provides excellent information on the difficult nature of this issue.

Given the promising narrative about the challenges facing physicians, there are a few areas where we believe state medical boards may be encouraged to focus more on enforcement of mandates than on careful evaluation of this complicated part of many physicians’ medical practice. For example, the Draft Policy appropriately advises that “[a]llegations of inappropriate pain management will be evaluated on an individual basis.” But it is not clear how that will be implemented under a directive that “[w]henver federal laws and regulations differ from those of a particular state, the more stringent rule is the one that should be followed.” Questions we ask that FSMB consider include the following: is that meant for the state medical board or the physicians who are regulated by the board. Who interprets stringency, and under what measures? This is one area where further clarification would appear necessary to clarify how the FSMB intends for state medical boards to act.

3. Does the statement fairly balance the interests of patients with state medical boards’ obligation to protect the public safety?

As noted above, the Draft Policy does a very good job of recognizing the complicated nature of treating pain – and the fact that patients sometimes have difficulty in providing all relevant information to their physician. The AMA agrees with the Draft Policy’s recommendations that opioid analgesics are one of several options for treating pain and helping patients maintain/regain function. This includes the careful consideration of whether to prescribe opioid analgesics as part of an overall treatment plan. It is the AMA’s position that any such use should be initiated as a trial – using a universal precautions approach.

The multiplicity of all of the new standards of care (e.g., including the use of informed consent and treatment agreements, drug screens and other tests, and requirements for referral), however, raise several potential areas where the balance may tip against ensuring prompt treatment. For example, these new requirements may be entirely appropriate for some patients, but may not be necessary for all patients – depending on the level of risk inferred from the patient’s unique medical history and co-morbidities, as well as the patient’s potential for abuse and diversion. That is the challenge posed by mandating new requirements. Specifically, a “one-size-fits all” approach invariably causes an imbalance. Therefore, the AMA is concerned that this could reduce patients’ ability to have their pain treated promptly in some cases – or at all if the new requirements discourage some physicians from seeing patients with chronic pain.

Questions we ask FSMB to consider include the following. Does FSMB distinguish, for example, whether there should be different standards for palliative care and patients with a terminal condition? In other words, should there be different standards for hospice patients receiving palliative care than a physician initiating opioid therapy for a patient with acute or chronic pain? Would not the protocol be different for treating a terminal patient because the physician would not be as concerned about the risk of drug dependency? Or does FSMB intend for its guidelines to apply to all physicians and all patients for all conditions?

Currently, the Draft Policy only recommends consultation with the state Attorney General “to identify any barriers to the effective use of opioids to relieve pain” while also carrying out appropriate law enforcement functions. The AMA understands that contemplated solutions to the nation’s prescription drug abuse and diversion epidemic have focused on the appropriate role of law enforcement. The AMA agrees that law enforcement has a role to play in helping identify and hold accountable illegal prescribing activity and pharmacies (including rogue internet-based sites) that enable such practices. The AMA believes, however, that the FSMB should recognize that the very complicated public health nature of this epidemic demands that state medical boards consult with the appropriate public health officials, department of health agencies and other health-related professions – including state medical societies – in considering the relative merits of the Draft Policy’s elements.

4. Is there any other information you think the statement should incorporate?

The AMA is pleased to see the Draft Policy discuss prescription drug monitoring programs (PDMPs) in the patient evaluation and monitoring sections. PDMPs have the potential to serve as a critical clinical tool in the fight against prescription drug abuse, misuse and diversion. Generally, however, physicians do not have access to reliable, real-time information about prescriptions patients have obtained (and filled) from other prescribers – particularly controlled substances. Thus, where the Draft Policy takes a good step in acknowledging that PDMPs use only is recommended “where available,” the challenges with PDMPs go far beyond availability.

The reality is that it has been only in the past couple of years that most states have finally passed state legislation establishing PDMPs. However, as you are most likely aware, the majority of PDMPs are not real-time, interoperable, or available at the point of care as part of physician’s workflow. Only five states provide data within 24 hours, according to the National Alliance for Model State Drug Laws (NAMSDL); one state provides data within three days; 32 states take up to a week to provide data; and nine states take between two weeks and one month to provide the same. With respect to interstate interoperability, NAMSDL reports that 43 states can legally share data across state lines, but only 20 can legally share data with other PDMPs.

Modernized PDMPs can provide physicians with a basic tool to make treatment determinations based on patient-specific needs. The AMA urges caution, however, that reducing drug use and preventing death cannot be fully achieved through well-meaning, but untested strategies. This includes requiring all prescribers to check an antiquated and poorly maintained PDMPs for all patients as a condition of treatment. If the PDMPs are “available,” but has inaccurate, incomplete or old data, it is not a useful tool in patient evaluation or monitoring.

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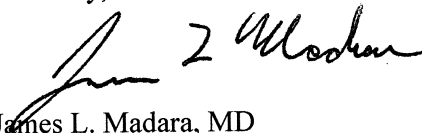
Therefore, we encourage the FSMB to work with the AMA and state medical societies in advocating for PDMPs that are reliable, real-time and available at the point of care as part of a prescriber's workflow. Optimally, PDMPs must be designed so that up-to-date information is immediately available when physicians are querying the database and considering a decision to prescribe a controlled substance. Furthermore, the AMA encourages the FSMB to advocate for PDMPs to be adequately funded, maintained and modernized. It is the AMA's position that this will ensure their long-term ability to help combat prescription drug abuse and diversion. Thus, while the AMA appreciates the FSMB's support for PDMPs, the AMA asks that the FSMB consider including in the Draft Policy a much more robust discussion of the conditions under which PDMP enhance physicians' practices and clinical decision making.

Conclusion

Clearly, there are many areas where the AMA and the FSMB can work together and play a powerful role in helping combat prescription drug abuse, misuse and diversion. The AMA believes that – with the clarifications and further review as recommended above – the Draft Policy will serve as an important resource for state medical boards as they, too, confront this national epidemic.

Thank you for the opportunity to provide our input into the FSMB's policy drafting process. 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: Steven J. Stack, MD