PROP
PHYSICIANS FOR RESPONSIBLE OPIOID PRESCRIBING

March 29, 2013

Dear State Medical Board Member:

I am writing to share the concerns of Physicians for Responsible Opioid Prescribing (PROP) about the Federation of State Medical Board's (FSMB) recently revised *Model Policy on the Appropriate Use of Opioid Analgesics in the Treatment of Pain*. We believe that if your state were to adopt the proposed policy it might encourage opioid overprescribing, potentially worsening the epidemic of opioid analgesic addiction and overdose deaths. We believe that this document minimizes opioid risks and encourages the highly controversial practice of treating chronic non-cancer pain (CNCP) with opioids. Furthermore, because it fails to suggest practical policies to reduce risky prescribing, we believe an important opportunity to assist your state in addressing this urgent public health crisis may have been lost.

Background

Over the past decade, a four-fold increase in prescribing of opioid analgesics has been associated with a four-fold increase in opioid related overdose deaths and a six-fold increase in individuals seeking treatment for addiction to opioid analgesics.[1] The growth in prescribing that caused (and continues to fuel) this epidemic was largely driven by an industry-funded campaign to encourage opioid prescribing for CNCP. This campaign minimized risks of long-term opioid use and exaggerated benefits.[2,3,4] An increasing body of medical literature now suggests that long-term opioid use is neither safe nor effective for many patients with CNCP.[5,6,7,8]

FSMB played a unique role in the campaign to encourage opioid prescribing for CNCP. In 1997, FSMB began collaborating with opioid advocacy organizations to promote opioid use for CNCP. Together they produced the first Model Policy. Like the current version, it encouraged the use of opioids for CNCP and wrongly suggested that opioids were underprescribed because of inappropriate fear of addiction.

In 2004, FSMB revised the 1997 Model Policy. Despite sharp increases in opioid prescribing that had occurred between 1997 and 2004, the 2004 Model Policy continued to suggest that opioids were being underprescribed for CNCP. In addition, the 2004 Model Policy went further, stating that medical boards should consider "undertreatment of pain" to be a "departure from an acceptable standard of practice," suggesting that state medical boards should sanction physicians for not treating CNCP with opioids.

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In February 2012, the Milwaukee Journal Sentinel (MJS) published a story about FSMB's financial relationships with opioid manufacturers and their role promoting aggressive opioid prescribing.[9] In May 2012, prompted by the MJS article, FSMB was included in a U.S. Senate investigation of financial relationships between organizations promoting opioid use and drug companies.[10]

Last December, a front page Wall Street Journal article also discussed FSMB's role in the opioid epidemic. The Wall Street Journal wrote:

> *In 1998, the Federation of State Medical Boards released a recommended policy reassuring doctors that they wouldn't face regulatory action for prescribing even large amounts of narcotics, as long as it was in the course of medical treatment. In 2004 the group called on state medical boards to make undertreatment of pain punishable for the first time.*
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> *That policy was drawn up with the help of several people with links to opioid makers, including David Haddox, a senior Purdue Pharma executive then and now. The federation said it received nearly $2 million from opioid makers since 1997.*[11]

Specific concerns about the revised Model Policy

The revised Model Policy bears a striking resemblance to the previous version. It retains the same statements and misinformation that have been publicly criticized by health officials and medical experts. For example, the Model Policy continues to state and/or imply the following:

- Opioid use for CNCP should be encouraged.
- Opioids are safe and effective for CNCP.
- "Risk of addiction is relatively low unless the patient has additional risk factors."
- Physicians should be sanctioned for "nontreatment" or "undertreatment" with opioids.
- Pain patients that attribute aberrant drug use behavior to worsening pain may be suffering from "**pseudoaddiction**" and should have their dose increased.

Our concerns are not limited to misinformation contained in the Model Policy that might encourage overprescribing. We are equally troubled by evidence-based content that is absent from the Model Policy. Over the past few years, expert opinion, reflected in multiple editorials in leading medical journals, is that a substantially more cautious stance toward opioid prescribing for CNCP is now needed.[12,13,14,15,16,17,18,19] These concerns have prompted the Centers for Disease Control as well as state and city health departments to ask clinicians to reserve opioids as a last resort when alternative treatment options have failed and to keep opioid doses under ~100mg morphine equivalents.[20,21,22] Yet, the revised Model Policy makes no mention of increasing concerns about long-term and high dose opioid use for CNCP.

The following important information that would promote cautious and responsible opioid use is absent from the Model Policy:

- Opioids should be reserved for CNCP patients that have failed safer options.
- Evidence of long-term safety and effectiveness is lacking.
- Opioids may worsen pain in some patients, a condition known as hyperalgesia.
- High doses of opioids (>100mg MED) are associated with increased risk of overdose death and other serious adverse events.
- Addiction in CNCP patients is not uncommon.
- Discontinuing long-term opioid therapy can be difficult, even for patients that are not addicted.
- Prescribing opioids in combination with benzodiazepines is especially dangerous.

The revised Model Policy contains a few new paragraphs suggesting that physicians utilize "universal precautions", risk stratification tools, and other techniques promoted by the opioid industry's key opinion leaders as a "new paradigm" that ensures safe and effective opioid prescribing. While all patients on long-term opioid therapy should be monitored closely, it is improper to suggest that these practices will prevent pain patients from becoming addicted to opioids.

Notably absent from the Model Policy is practical guidance for state medical boards to improve their monitoring of prescribers. Although the Model Policy now encourages physicians to check a prescription drug-monitoring program (PDMP) when prescribing opioids (a suggestion we strongly support), there is no suggestion for state medical boards to use their state PDMP to monitor risky prescribing practices of their physicians.

Summary

With the exception of a few new paragraphs encouraging closer monitoring of pain patients, the new Model Policy is nearly identical to the widely criticized 2004 version. The Model Policy continues to encourage physicians to prescribe a treatment that experts believe is harming many pain patients and is fueling an epidemic of addiction and overdose deaths.

As agencies charged with protecting the public from reckless and risky medical practices, state medical boards are in a unique position to help reduce opioid overprescribing. FSMB should be offering your board practical guidance on addressing this urgent public health crisis instead of promoting the exact practice that caused and fuels the opioid epidemic.

Please let FSMB know that the policy requires substantial changes.

Sincerely,

Andrew Kolodny, MD.

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