REPORT OF THE BOARD OF DIRECTORS

Subject: **Report on Resolution 18-1: Acute Opioid Prescribing Guidelines**

Referred to: **Reference Committee A**

Adopted by the FSMB House of Delegates in April 2018, Resolution 18-1: Acute Opioid Prescribing Workgroup and Guidelines, submitted by the State Medical Board of Ohio, originally called for the creation of a workgroup and model guidelines, but was substituted with the following resolution:

> *Resolved*, that the Federation of State Medical Boards (FSMB) perform a comprehensive review of acute opioid prescribing patterns, practices, federal laws and guidance (including Centers for Disease Control and Prevention guidelines), state rules and laws across the United States, available data, and present a report to the House of Delegates at the Annual Meeting in 2019.

The following is a status report on work to date toward achievement of the resolution.

Overview

Drug overdose deaths has been on the rise since 1999, with more than 399,000 deaths involving any opioid, including prescription and illicit opioids, between 1999-2017. In 2017, there were 5.2 opioid overdose deaths per 100,000 people as a result of commonly prescribed opioids (natural and semi-synthetic opioids and methadone).[i]This escalating public health epidemic has led to a wave of implementation of new laws and regulations at the federal and state level in an effort to curb substance use disorder.

These efforts have ranged from implementing or upgrading prescription drug monitoring programs to mandating prescribers complete continuing medical education on opioids and prescribing practices to imposing guidelines on prescribing opioids for the treatment of chronic pain. Most recently, legislatures and regulatory agencies are examining and adopting policies to limit the prescribing of opioids to treat acute pain.

Federal Laws and Guidance

Centers for Disease Control (CDC) Guidelines

In 2016, the CDC published guidelines on opioid therapy for chronic pain after a growing concern about the overprescribing of opioids for pain management. These recommendations were originally developed to provide recommendations for primary care clinicians treating chronic pain in patients 18 years or older, except in instances of active cancer treatment, palliative care, or end-of-life care.

The *Guidelines* recommend that when opioids are started to treat chronic pain, clinicians should use caution when prescribing at any dosage. Specifically, clinicians should prescribe the lowest effective dosage, should carefully reassess evidence of individual benefits and risks when

considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

Some of the recommendations within the *Guidelines* are relevant for acute care setting, but are not the focus of the guidelines. For the use of opioids to treat acute pain, the *Guidelines* recommend that clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Generally, three days or less will often be sufficient, while more than seven days will rarely be needed.[iiiii] The *Guidelines* refer readers to other sources for prescribing recommendations within acute care settings. Despite the limited scope, the *Guidelines* have been highly influential in shaping state and federal policies and strategies to support safe prescribing in both acute and chronic pain treatment settings.

Pain Management Best Practices Inter-Agency Task Force

Created as a result of the Comprehensive Addiction and Recovery Act (CARA) of 2016, the Pain Management Best Practices Inter-Agency Task Force (Task Force) aims to determine if there are gaps or inconsistencies between best practices for the management of acute and chronic pain. The Task Force consists of 29 subject experts and was convened by the Department of Health and Human Services, in conjunction with the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the White House Office of National Drug Control Policy (ONDCP). It drafted a report and recommendations in December 2018, which once finalized after a public comment period, will be submitted to Congress in 2019.

The Task Force acknowledges that "the optimal management of acute pain should include establishing a diagnosis and overall treatment plan with continuity of care" and that "it is vital to consider a risk-benefit analysis with a risk assessment approach to prove the best possible patient-centered outcome while mitigating unnecessary exposure." As a result, the Task Force believes that when controlling acute pain with medications, it should be for the shortest period of time necessary, as well as administered at the lowest dose required to optimally control the pain or improve function.[iv] The Task Force recommends that "the type, dose, and duration of opioid therapy should be determined by treating clinicians according to the individual patient's needs and pain condition."

State Laws and Regulations

In performing a comprehensive review of prescribing patterns and practices, the FSMB conducted an Opioid Policy Survey to its' 70 allopathic and osteopathic boards on a wide variety of strategies deployed to combat the opioid epidemic. Fifty-five out of 70 state boards, resulting in a response rate of 79 percent.

Prescribing Limits

With the opioid epidemic growing across the country, states and regulatory agencies in recent years have turned to examining not only the use of opioids to treat chronic pain, but also the use of opioids for the treatment of acute pain. Since 2015, more than 30 states have set limits on the quantity and dosage of opioids that can be prescribed to treat acute pain. These limits vary across

states in terms of how they established and whether they are set by a number of days' supply and/or daily morphine milligram equivalent (MME). In addition to these variations, states also vary in terms of exceptions to the limits.

How these limits are imposed vary state by state; some are done through statute, some through rules, and some through guidelines or policy. Some states impose limits using two or three of these methods. For the treatment of chronic pain, opioid prescribing limits are set in statute by 59 percent of boards with prescribing limits, while they are set in rules by 59 percent and in guidelines or policy by 18 percent. Opioid prescribing limits for the treatment of acute pain are set in statute by 76 percent of boards, while they are set in rules by 32 percent of boards and in guidelines or policy by 4 percent[v] (See Figure 1).

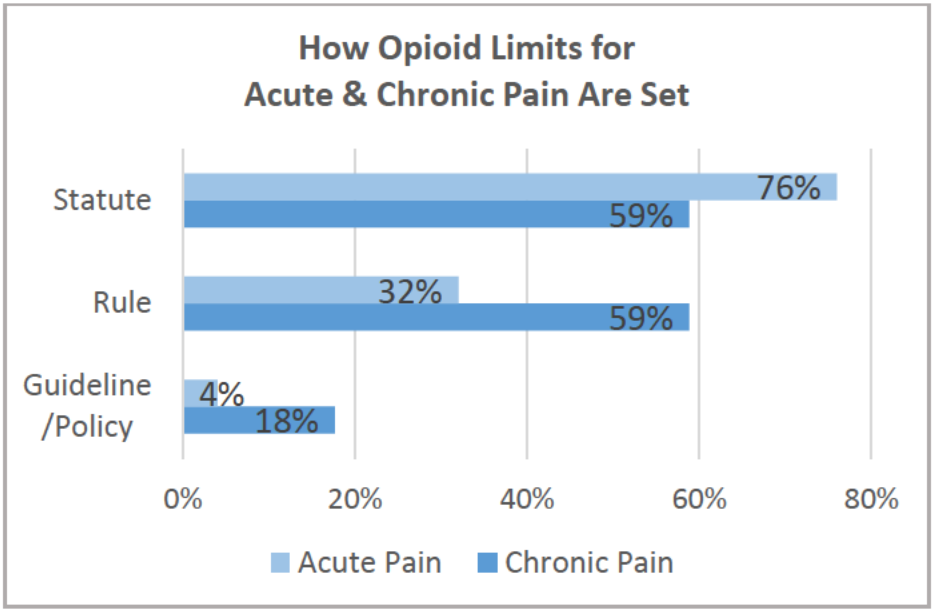

Figure 1: How Opioid Limits for Acute & Chronic Pain are Set
(*Source: Federation of State Medical Boards Opioid Policy Survey, 2019)*

As states have adopted limits on prescribing, there has been great difference between what the actual limits are and whether they apply to all prescriptions or certain situations. In some states, there are multiple limitations based upon the situation. Out of the states with opioid prescribing limits, 22 states have a 7-day supply limit on certain prescriptions, such as initial prescriptions for adults, any prescription for a minor, all opioid prescriptions for acute pain, or prescriptions for an emergency department, urgent care, or walk-in clinic visit, among other situations. Other states have limits of 14 days (two states), five days (five states), three to four days (four states).

Limits are not always confined to a certain days' supply threshold, but instead based upon daily MME. Five states have adopted limits that prohibit prescriptions from exceeding certain daily MME, such as 100 MME/day for acute pain in Maine, 30 MME/day for all circumstances when opioids are prescribed for acute pain in Ohio, or various daily MME thresholds based upon pain level. Four states, instead of setting a specific days' supply limit or daily MME threshold, require that the lowest necessary dose be prescribed for the shortest duration for prescriptions containing opioids (See Figure 2).

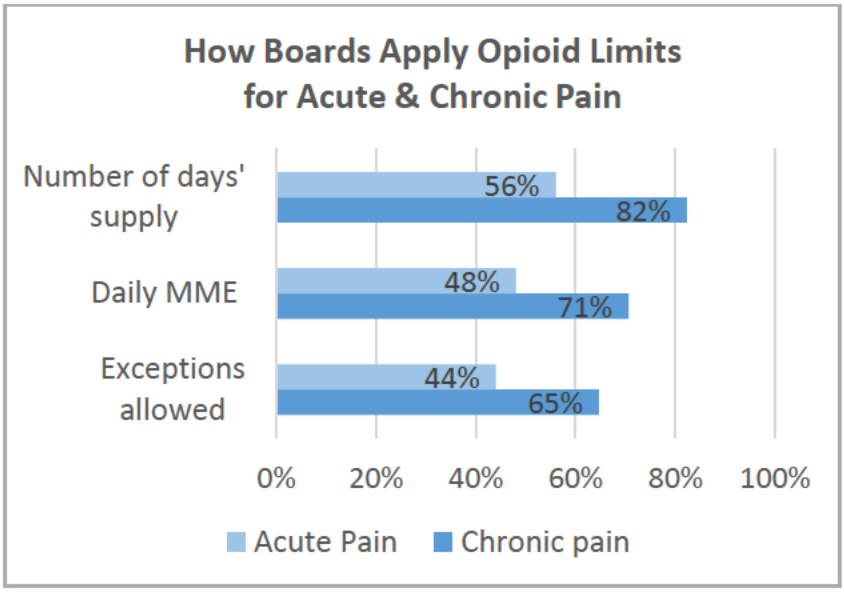

Figure 2: How Boards Apply Opioid Limits for Acute & Chronic Pain
(*Source: Federation of State Medical Boards Opioid Policy Survey, 2019)*

While states vary amongst themselves on the prescribing limits, states also vary in regards to exceptions to the limits. Generally, there are six different exception categories to the number of days' supply and daily MME limits. These categories include chronic pain, cancer, palliative care, hospice care, provider judgment, and treatment for substance use disorder or medication assisted treatment. Additionally, there are other exceptions that are not as frequently carved out, including long-term care facilities, burn treatment, post-operative care, and in-patient setting.[vi]

Multifaceted Approach

State executives, legislatures and regulatory agencies recognize that the response to the growing opioid epidemic must be a multifaceted approach. In recent years, there has been widespread enactment and promotion of wide-ranging approaches aimed at reducing the use of opioids, including mandatory PDMP queries, permitting regulatory agencies to utilize PDMP data, requiring electronic prescribing (e-prescribing) of controlled substances, requiring diagnosis codes for opioid prescriptions, and communication and educational resources for licensees and the public.

As of January 2019, 44 states have implemented some form of a PDMP universal use mandate, each varying in scope and strength.[vii]According to the Opioid Policy Survey, each board that responded utilizes the data from the state's PDMP. Eleven percent of respondents require a subpoena prior to accessing PDMP data. Based on the PDMP data accessible to medical boards, 76 percent of boards have taken disciplinary action against licensees[viii] (See Figure 3).

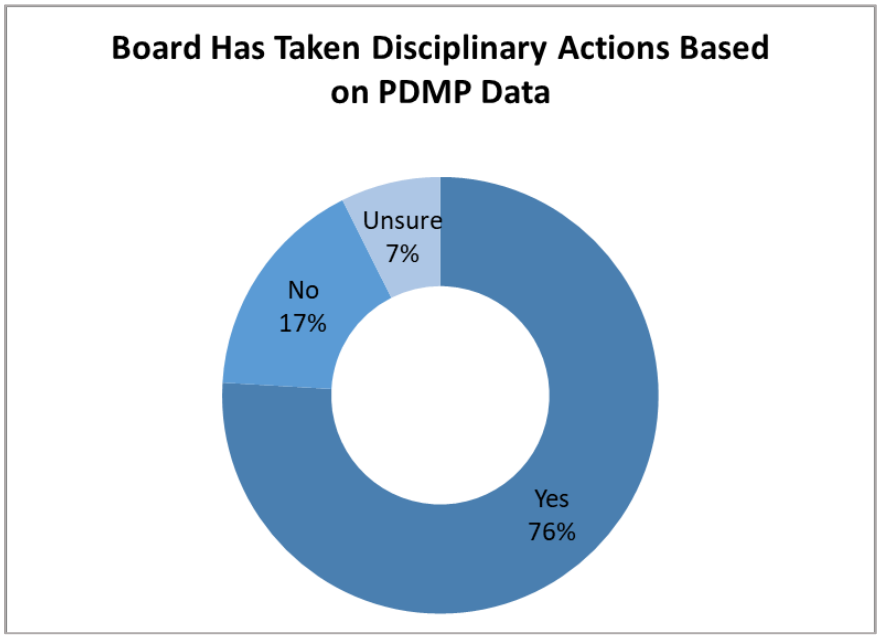

Figure 3: Board Has Taken Disciplinary Actions Based on PDMP Data
(*Source: Federation of State Medical Boards Opioid Policy Survey, 2019)*

States have also taken efforts to enact requirements for opioid prescriptions related to e-prescribing and diagnosis codes. Twenty-five percent of the Opioid Policy Survey respondents stated that their states require e-prescribing for opioid prescriptions, while 43 percent of respondents stated that diagnosis codes are required for opioid prescriptions.[ix]

The Opioid Policy Survey found that 91 percent of responding boards provide communication or educational materials on opioid prescribing to licensees, while 49 percent of respondents provide materials to the public. Additionally, 11 percent of respondents provide materials to other populations, such as state legislators, medical schools, medical societies, and other regulatory boards.

Collaborative Efforts to Address Opioid Epidemic

When addressing the opioid epidemic, state medical boards have recognized that efforts should not be limited to only their specific board. Instead, there have been efforts by medical boards to work with other regulatory boards and agencies within their state to determine best practices. According to the FSMB Opioid Policy Survey, 80 percent of medical boards collaborate with the Board of Pharmacy in their state on issues related to the opioid epidemic. Medical boards also indicated that they collaborate with other departments and regulatory boards, such as the Department of Health (76 percent), Board of Nursing (56 percent), Board of Dentistry (47 percent), Board of Podiatry (40 percent), and other agencies (24 percent). For states that have separate allopathic and osteopathic boards, 42 percent responded that there are collaborative efforts between the boards[x] (See Figure 4).

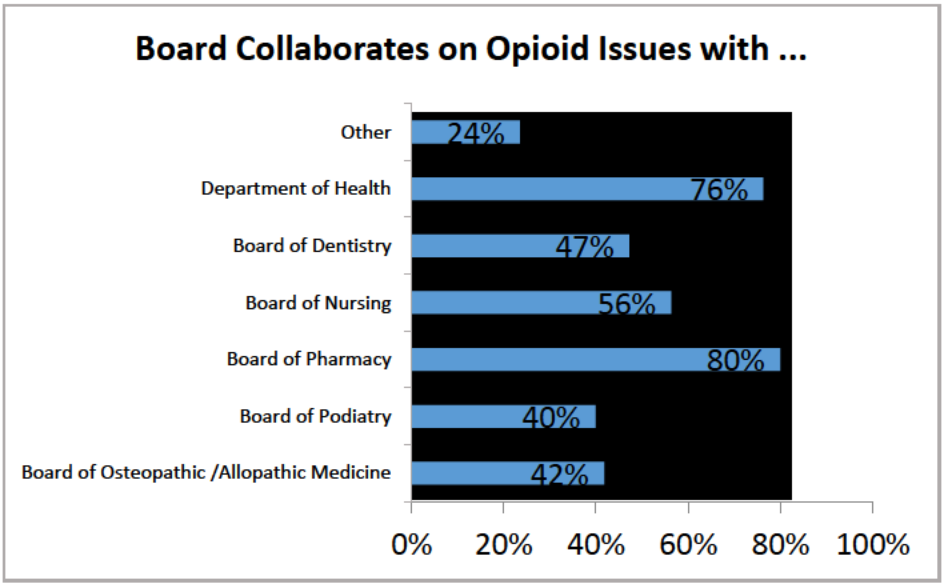

Figure 4: Board Collaboration on Opioid Issues
(*Source: Federation of State Medical Boards Opioid Policy Survey, 2019)*

Data

As the number of states continues to grow that are imposing limits on the prescribing of opioids, more studies are being conducted and data is being dispersed on the results of these efforts.

According to Shah et al., the probability of long-term opioid use increases most in the first days of treatment, particularly after five days or one month of opioids have been prescribed. Based on their study, the largest incremental increases in the probability of continued opioid use were observed when the first prescription supply exceeded 10 or 30 days, when a patient received a third prescription, or when the cumulative dose was greater than 700 MME.[xi]

The State Medical Board of Ohio's initiatives to address opioid misuse and overdose, in collaboration with other regulatory agencies in the state, began in 2011. These initiatives have included increased regulation of pain management clinics, mandatory PDMP queries, and most recently guidelines for chronic, acute, and subacute pain. The State Medical Board of Ohio first adopted acute pain guidelines in 2016, which called for consideration of non-opioid treatment first, with reevaluation after 14 days and again at six weeks of treatment. These guidelines were followed in 2017 by a seven-day supply limit (five-day for minors) and 30 MME/day limit, as well as including ICD-10 diagnosis codes on opioid prescriptions. Lastly, in 2018, the board began requiring ICD-10 diagnosis codes on all controlled substance prescriptions.

Each of these initiatives have led to a reduction in the number of prescriptions. In between the announcement of the proposed limits in 2017 and when they went into effect five months later, there was a 41 percent decrease in more-than 30 MME/day prescriptions and a 20 percent increase in less-than 30 MME/day prescriptions.[xii]The result of these initiatives collectively has been a 28 percent reduction in opioid prescriptions and 88 percent reduction in multiple provider episodes.

While there is evidence suggesting the benefits of imposing limits on opioids for acute pain, the Pain Management Best Practices Inter-Agency Task Force cautions about the efficacy of imposing

limits on opioid dosage, as the therapeutic window is highly variable. The Task Force cites that in a recent study of the risk of death related to opioid dose in North Carolina that "dose-dependent opioid overdose risk among patients increased gradually and did not show evidence of a distinct risk threshold. Much of the risk at higher doses appears to be associated with co-prescribed benzodiazepines."[xiii]

Although opioids are effective in treating acute pain, patients can be at risk of becoming new chronic opioid users in the postsurgical setting. According to Brummett et al., among a population of opioid-naïve patients who were given opioids to treat acute pain after a surgery, about six percent became chronic users.[xiv]In that same study, those that were at a higher risk of becoming a chronic opioid user were patients with tobacco use, alcohol and substance abuse disorders, anxiety, depression, other pain disorders, and comorbid conditions. This finding stresses the importance of initial patient-physician interaction, as well as appropriate follow-up to assess the treatment plan.

Other strategies to combat the opioid epidemic, such as the utilization of PDMP data prior to prescribing, has led to altered prescribing habits by clinicians. According to Baehren et al. when PDMP data is used in emergency departments, 41 percent of cases had altered prescribing after the prescriber reviewed the PDMP, with 61 percent of those patients receiving fewer or no opioids than originally planned and 39 percent receiving more opioids than initially planned.[xv]

Ongoing Efforts

As the opioid epidemic continues through the United States, the Federation of State Medical Boards will continue to provide resources to state medical boards on best practices and guidelines to address substance use disorder. Among these efforts will be expanding the reach of this report by creating a new platform on the FSMB's website dedicated to opioid (both acute and chronic) prescribing. This platform will consist of the findings in the report, including any available outcome data, legislative resources, state comparison charts, as well as highlight and promote FSMB's Guidelines for the Chronic Use of Opioid Analgesics and Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office and any other model guidelines that have been released by various agencies and organizations.

Additionally, during the FSMB's 2019 Annual Meeting, as well as future Annual Meetings, sessions and forums will be held on the opioid crisis, including presentations by state medical boards on their response to the epidemic.

ITEM FOR ACTION:

No action required; report is for information only.

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[i] Centers for Disease Control (CDC). "Opioid Data Analysis and Resources," https://www.cdc.gov/drugoverdose/data/analysis.html

[ii] Centers for Disease Control (CDC). "CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016," https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm

[iii] Howard, MD Ryan et al. "Reduction in Opioid Prescribing Through Evidence-based Prescribing Guidelines," *JAMA Surg*. 2018;153(3):285-287. doi:10.1001/jamasurg.2017.4436. Published online December 6, 2017.

[iv] Pain Management Best Practices Inter-Agency Task Force."Draft Report on Pain Management Best Practices," https://www.hhs.gov/ash/advisory-committees/pain/reports/2018-12-draft-report-on-updates-gaps-inconsistencies-recommendations/index.html#fnote-129

[v] Federation of State Medical Boards. "Opioid Policy Survey," January 2019.

[vi] Federation of State Medical Boards. "Acute Pain Prescribing Statutes."

[vii]Brandeis University PDMP Training and Technical Assistance Center. "Listing of Mandatory Query Conditions." http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20190115.pdf

[viii] Federation of State Medical Boards. "Opioid Policy Survey," January 2019.

[ix] Federation of State Medical Boards. "Opioid Policy Survey," January 2019.

[x] Federation of State Medical Boards. "Opioid Policy Survey," January 2019.

[xi] Shah, Anuj et al. "Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015," *MMWR.* 2017; 66(10). Published March 17, 2017.

[xii] State Medical Board of Ohio. "Initiatives to Address Opioid Misuse and Overdose." November 2018.

[xiii]Pain Management Best Practices Inter-Agency Task Force. "Draft Report on Pain Management Best Practices," https://www.hhs.gov/ash/advisory-committees/pain/reports/2018-12-draft-report-on-updates-gaps-inconsistencies-recommendations/index.html#fnote-129

[xiv]Brummett, Chad M. et al. "New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults," *JAMA Surg.* 2017;152(6):e170504. doi:10.1.001/jamasurg.2017.0504. Published online April 12, 2017.

[xv]Baehren, DF et al. "A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing," Ann Emerg Med. 2010 Jul;56(1):19-23.e1-3. doi: 10.1016/j.annemergmed.2009.12.011. EpubJanuary 4, 2010.