MEMORANDUM

TO: Sallie Debolt, State Medical Board of Ohio

FROM: Danielle Dillard, Regulatory Policy Advocate

DATE: August 17, 2018

RE: **CSI Review – Prescribing for Subacute and Chronic Pain (OAC 4731-11-01, 4731-11-02, 4731-11-14, 4731-21-01, 4731-21-02, 4731-21-03, 4731-21-04, 4731-21-05, and 4731-21-06)**

On behalf of Lt. Governor Mary Taylor, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

This rule package contains six rescinded rules, two amended rules, and one new rule proposed by the State Medical Board of Ohio (Board). The rule package was submitted to the CSI Office on June 14, 2018 and the public comment period was held open through June 28, 2018. Four comments were received during this time.

The rules being rescinded in this package set forth the requirements for physicians to follow in prescribing medication for chronic pain. They are being replaced by the proposed rule, Ohio Administrative Code (OAC) 4731-11-14. The new rule requires physicians to consider non-medication and non-opioid treatment options when treating subacute and chronic pain, and to offer a naloxone prescription to a patient receiving opioids under certain circumstances. If a physician is going to prescribe opioids, then they must comply with varying requirements based on the Morphine Equivalent Dose (MED). The new rule does not apply to opioid prescriptions for

patients in hospice care, patients with terminal conditions, or inpatient prescriptions under Pharmacy Board statutes.

The two rules being amended make only nonsubtantive changes. OAC 4731-11-01 adds definitions for medication therapy management, subacute pain, and chronic pain, and modifies the definition of acute pain to clarify that it lasts six weeks or less. OAC 4731-11-02 corrects the reference to Pharmacy Board rules which must be followed for controlled substance prescriptions.

The Board worked closely with the Governor's Cabinet Opiate Action Team, and the Boards of Nursing, Dentistry, and Pharmacy to draft the rules. During early stakeholder outreach, the Board held public Policy Committee meetings where the rules were discussed, and circulated the rules to all prescriber licensees. It received seventeen comments during early outreach which were discussed in detail at public meetings with the Policy Committee and full Medical Board. The comments received touched on a variety of subjects. The Ohio State Medical Association (OSMA) recommended the elimination of written informed consent, Ohio Health raised concerns over the applicability of the grandfather provisions, several commenters suggested eliminating the face-to-face visit requirement when pain management specialists are needed, and seven commenters recommended including a co-prescription for naloxone at 50 MED to reflect the Centers for Disease Control and Prevention (CDC) guidelines. The Medical Board ultimately made just one change based on the feedback. It added a provision requiring physicians to consider offering a naloxone prescription at 50 MED to mitigate risk of overdose.

Four comments were received during the CSI public comment period, and three were substantive. One physician raised concerns over toxicology testing, and suggested having mandatory testing once opioid prescribing becomes chronic. The Board noted that there are currently toxicology testing provisions in the rules, and it is mandatory above certain MED. Another physician suggested that a naloxone prescription be required, rather than considered, to be offered to patients receiving opioid treatment. The Board notes that the rules are intended to establish minimum standards, and allow physicians and physician assistants room to apply their medical judgment.

The Northeast Ohio Hospital Consortium noted their general support for the rules, but raised concerns over the informed consent, consultation with experts, and thresholds for increased monitoring provisions. The Consortium noted that obtaining informed consent at 50 MED is burdensome and redundant, given that physicians would have already informed patients of risks associated with opioids due to other rule provisions. It stressed that this will reduce the already limited time physicians have with patients in clinical settings. With regard to consultation with experts, the Consortium suggests an addictionologist be engaged prior to opioid treatment with all patients who have a prior or current substance abuse disorder. Lastly, the Consortium recommends

changing "periodic" follow-up assessments to required follow-up assessments every ninety days, with telemedicine being permitted when necessary. The Board responded stating that rules are drafted to allow physicians and physician assistants to apply their medical judgment, and are not intended to dictate the exact manner in which care must be delivered. It noted that all of the concerns raised by the Consortium are addressed by the rules, and declined to make further changes.

The rules will impact the Board's licensees who are authorized to prescribe controlled substances, including opioids. This includes physicians holding a M.D., D.O., or D.P.M. license, and physician assistants who are authorized to prescribe. Prescribers who prescribe opioids for subacute and chronic pain will need to be aware of the checkpoints at 50, 80, and 120 MED and may need to see patients receiving these prescriptions more frequently. They will also need to obtain consultations with specialists and implement drug screening in certain circumstances, and consider offering a naloxone prescription under certain circumstances. Physicians and physician assistants who violate the rules will be subject to disciplinary action, which could include a monetary fine. The Board asserts that any adverse impact is justified because of the serious opioid epidemic in Ohio, and because the rules serve to limit the number of opioid analgesics that are available while providing additional care and resources to patients receiving high amounts of opioids.

Recommendations

For the reasons described above, the CSI Office has no recommendations on this rule package.

Conclusion

Based on its review of the proposed rule package, the CSI Office recommends the State Medical Board of Ohio should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.