



MEMORANDUM

TO: Kimberly Anderson, Ohio State Medical Board

FROM: Travis Butchello, Regulatory Policy Advocate

DATE: June 16, 2017

RE: **CSI Review –Limits for Prescribing of Opioids for Acute Pain (4731-11-01, 4731-11-02 and 4731-11-13)**

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 consists of two amended and one new rule proposed by the Ohio State Medical Board. The rule package was submitted to the CSI Office on May 15, 2017 and the public comment period was held open through May 26, 2017. Seventy one comments were received during this time. Responses to the comments were provided on June 2, 2017.

The rules add definitions for acute pain, explain the morphine equivalent daily dose (MED), exempt conditions from the rules, and detail reporting requirements. The new rule includes provisions which set the amount of MED allowed per day at 30, which may be exceeded if the prescriber deems it clinically necessary and documents their reasoning in the patient's medical record. It also limits opioid prescriptions for acute pain to 7 days for adults and 5 days for minors but allows the limits to be exceeded if a prescriber also documents their reasoning in the patient's medical record. Lastly, the new rule requires that a patient and the parent or guardian of a minor be advised of the benefits and risks of an opioid medication and potential for addiction. The BIA states that the purpose of the rules is to reduce the frequency and amount of opioids prescribed for

acute pain, while preserving the ability for providers to exercise professional discretion and go beyond the limits when they deem it necessary and with proper documentation for accountability.

The Board stated in the BIA that it collaborated with the Governor's Cabinet Opiate Action Team, Board of Nursing, Dental Board, and the Board of Pharmacy to draft the rules. As part of their early stakeholder outreach process, the Board discussed the draft rules at their policy meeting on April 12, 2017 where the public was able to participate in the discussion of the rules. On April 13, 2017 the Board distributed the rules to prescriber licensees, including physicians, and placed the rules on their website for comment. During this process, the Board received 189 comments from the public and interested parties. On May 10, 2017 the Board discussed proposed amendments obtained through the stakeholder outreach process. Specifically, there were approximately 29 comments in favor of the rules, 106 raised concerns about prescribing limits regarding the length of the prescription and MED amount, 27 raised privacy concerns regarding the ICD-10 diagnosis code reporting requirement, and the remaining comments outlined concerns regarding overly burdensome documentation requirements, additional administrative costs, and costs to alter or change electronic controlled substance reporting systems. The majority of comments received referenced the 30 MED limit and primarily argued that the limit was too low and prescribers should be given the discretion to go above the limit under certain circumstances to address a patient's needs on a case-by-case basis. From discussions with stakeholders, the Board made changes to rule 4731-11-13 to include exceptions where the limit may be exceeded.

Seventy one comments were received during the CSI public comment period and contained the same issues raised during the early stakeholder outreach process. In addition, some comments were not directly related to the rules but rather expressed overall discontent with opioid prescribing restrictions in general and others were made based upon a misinformed interpretation of the rules. Notably, the Ohio State Medical Association expressed discontent with the ICD-10 diagnosis code requirement (also referenced in the Pharmacy Board rules), the 30 MED limit, and 7 and 5 day duration limits for adults and minors respectively. The Board responded that the documentation requirements to exceed the MED and duration limits are straightforward and that the Board generally leaves the details of documentation up to the discretion of the prescriber and the Pharmacy Board.

The rules impact licensees of the Medical Board who are authorized to prescribe opioids in the state. These individuals include physicians holding an M.D., D.O., or D.P.M. license and physician assistants. The Board states in the BIA that the rules impact these prescribers as they will need to see patients more often to maintain acute pain treatment with an opioid analgesic medication. In addition, prescribers will need to allocate sufficient time and means to input a diagnosis code and prescribers who violate the rules may be subject to a monetary fine as part of their discipline. Any monetary discipline imposed by the Board is regulated and quantified in ORC 4731.225. The Board believes that the regulatory intent justifies the adverse impact on business because many individuals who have become addicted to opioids began their journey when they were given their first pill, mostly through a valid prescription. The opioid epidemic in

Ohio has claimed thousands of lives and limiting the number of opioid analgesics that are available, along with limiting the amount and duration of the prescription, will hopefully reduce the amount of opioids that are used in an inappropriate manner.

Recommendation

For the reasons explained above, this office does not have any recommendations regarding this rule package.

Conclusion

Based on the above comments, the CSI Office concludes that the Ohio State Medical Board should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.