



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

MEMORANDUM

TO: Kimberly Anderson, State Medical Board of Ohio

FROM: Jacob Ritzenthaler, Regulatory Policy Advocate

DATE: November 13, 2019

RE: **CSI Review – Subacute and Chronic Pain Rules (OAC 4731-11-01 and 4731-11-14)**

On behalf of Lt. Governor Jon Husted, 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 Board as provided for in ORC 107.54.

Analysis

This rule package consists of two amended rules submitted by the State Medical Board of Ohio (Board). The rule package was submitted to the CSI Office on March 21, 2019, and the public comment period was held open through April 10, 2019. Eleven comments were received during this time. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI office on March 21, 2019.

The rules provide definitions for certified hematologists and certified oncologists and exempt those professions from the prohibition against prescribing opioids in excess of an average of 120 Morphine Equivalent Dose (MED). According to the BIA, in 2018, the Board became aware of two issues that were causing unintended consequences and delays for patients. First, the Board became aware, through interested parties, that non-terminal cancer patients often had pain which required pain medication that exceeded the 120 MED average daily dose, and these patients were experiencing delays seeing board-certified pain management specialists and board-certified hospice and palliative care specialists. Exempting board-certified hematologists and oncologists from the prohibition on prescribing in excess of 120 MED allows those physicians to provide prescriptions to their non-

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terminal cancer patients without delay. Additionally, the Board became aware that the definition of “terminal” was also causing delays for patients. State law requires a second opinion for determining that a patient has a terminal condition. This was resulting in a delay for these patients in obtaining appropriate pain relief. The proposed definition of terminal condition removes this requirement for a second opinion.

As part of early stakeholder outreach, the Board received feedback on the unintended consequences of the rule from various physicians and the Ohio Hospital Association. The Board also consulted with Dr. Mark Hurst of the Department of Mental Health and Addiction Services, Dr. Clint Koenig of the Ohio Department of Health, and Dr. Amol Soin, a pain management physician and member of the Medical Board.

Eleven comments were received during the CSI public comment period. The Board provided CSI with a response to comments on August 22, 2019. The Board determined some comments warranted further revision to the rules and involved, in general, prescribing in excess of 120 MED and the definition of “terminal condition.” For example, the Board will amend OAC 4731-11-01 (X) and (Y) to define Board certification in oncology and Board certification in hematology as recommended by the Ohio Hospital Association. The Board will also amend 4731-11-04 to mitigate the issue referral redundancy in 4731-11-04(C) and (D) as suggested by a stakeholder, and the term “incurable cancer” will be used in place of “terminal cancer” in 4731-11. In addition to these additional amendments, the Board will correct a citation error in 4731-11(I) to refer to OAC 4729-17-01, and added a definition of “board certification in pain medicine” as 4731-11-01(Z).

The rules impact licensees of the Medical Board 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. The Board identified the adverse impact as potential disciplinary action resulting in civil penalties for noncompliance. However, the amendments will lessen the adverse impact by allowing board-certified hematologists and oncologists to prescribe higher doses to their cancer patients when necessary to relieve pain. In addition, the amendments will eliminate the requirement for a second opinion to determine that a patient has a terminal condition. The Board justifies these rules because the State has a compelling interest in promoting safe treatment of pain while avoiding risks of harm to patients.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that the State Medical Board of Ohio should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.