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Common Sense Initiative

Mike DeWine, Governor Jon Husted, Lt. Governor Joseph Baker, Director

MEMORANDUM

то:	Kimberly Anderson, State Medical Board of Ohio
FROM:	Jacob Ritzenthaler, Business Advocate
DATE:	November 29, 2022
RE:	CSI Review – Controlled Substances (OAC 4731-11-03, 4731-11-04, and 4731-11-04.1

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 above mentioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Department as provided for in ORC 107.54.

<u>Analysis</u>

This rule package consists of one amended rule, one new rule, and two rescinded rules proposed by the State Medical Board of Ohio (Board). This rule package was submitted to the CSI Office on September 22, 2022, and the public comment period was held open through October 14, 2022. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on September 22, 2022.

Ohio Administrative Code (OAC) Chapter 4731-11 establishes requirements for the utilization of controlled substances. OAC 4731-11-03 concerns the use of anabolic steroids and Schedule II controlled substances, including the purposes for which these substances may or may not be used and procedure for violations. The rule is amended to include mental status examinations before utilizing controlled substances, update the types of symptoms which necessitate treatment with controlled substances, and correct typographical mistakes. OAC 4731-11-04 is a new rule that replaces an existing rule and sets forth requirements for the utilization of Schedule III and IV

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controlled substances for treating obesity. The rule sets forth requirements for activities to be completed before treatment, assessments and prescription of controlled substances, and violations of the rule requirements. OAC 4731-11-04.1 is proposed for rescission, as the content has been shifted to new rule OAC 4731-11-04.

During early stakeholder outreach, the Board sent the rules to industry stakeholders for feedback, including the Ohio State Medical Association, Ohio Association of Physician Assistants, State Pharmacy Board, Physician Assistant Policy Committee of the State Medical Board, Ohio Osteopathic Association, Ohio Hospital Association, and the Academy of Medicine of Cleveland and Northern Ohio. Prompted by stakeholder comments, the Board made changes to the rules that included updating requirements for weighing patients, weight reduction tracking, prescription limits, and remote monitoring of health information. During the CSI public comment period, the Board received comments from four stakeholders. In response to stakeholder concerns, the Board amended the rule to allow for pharmacists to furnish controlled substances in addition to physicians, allow for controlled substances to be used as a lifestyle intervention such as caloric restriction, and update patient examination metrics. The Board did not make changes based on comments that suggested the removal of requirements for prescribing controlled substances for chronic pain, stating that the requirements offer another avenue for chronic pain treatment other than opioids and should remain available to prescribers.

The business community impacted by the rules includes physicians and physician assistants. The adverse impacts created by the rules include the time and effort to comply with the prescribing requirements of the rules and to conduct periodic examinations. The Board states that the adverse impacts are necessary due to the health and safety risks posed by controlled substances.

Recommendations

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

Conclusion

The CSI Office concludes that the Board should proceed in filing the proposed rule with the Joint Committee on Agency Rule Review.