



MEMORANDUM

TO: Sallie Debolt, State Medical Board of Ohio

FROM: Sophia Papadimos, Regulatory Policy Assistant

DATE: April 24, 2015

RE: **CSI Review –Rules regarding Military Service, Limited Branches, Medical Board Meetings, and Controlled Substances (OAC 4731-1-02, 4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, 4778-1-02.1, 4731-6-35, 4731-7-01, 4731-9-01, 4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07)**

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 fifteen rules being proposed by the State Medical Board of Ohio pursuant to the five-year review requirement in statute. Seven new rules are being proposed, seven rules are being proposed with amendments, and one rule is being proposed for rescission. The rule package was submitted to the CSI Office on January 18, 2015 and the comment period was held open through February 6, 2015. Three comments were received during this time.

The rules in this package are from a variety of areas that the Medical Board regulates. Ohio Administrative Code (OAC) 4731-1-02 sets out general provisions applicable to the limited branches of medicine, specifically cosmetic therapy and massage therapy. The rule is being

amended for minor language changes. Six new rules are being proposed regarding military education, training, and service that is equivalency for licensure. Several administrative rules regarding meeting times and the recording of meetings are being amended for clarification purposes. The proposed amendments to OAC 4731-11-02, 4731-11-03, and 4731-11-05 consolidate into two rules the prohibitions/restrictions relating to schedule II controlled substance stimulants, cocaine hydrochloride, and performance enhancing steroids; resulting in the rescission of OAC 4731-11-05. OAC 4731-11-04 regulates the utilization of schedule III and IV controlled substance stimulants for weight loss purposes that have been FDA approved for short-term use (i.e., short-term anorexiant). Additionally, sections of the existing rule that refer to the use of controlled substance medications that in the past were FDA approved for weight loss and maintenance of weight loss were removed because those medications are no longer on the market. Proposed new rule 4731-11-04.1 was developed to regulate the use of new FDA approved controlled substance medications for chronic weight management (long-term anorexiants). The creation of this rule is intended to separate the regulations for long-term anorexiants from the regulations for short-term anorexiants. OAC 4731-11-07 provides an exception to the regulation of controlled substances used in research settings when specified conditions are met.

The adverse impacts created by this rule package include the time and costs associated with being in compliance and the penalties (e.g., fines, suspension, etc.) for non-compliance. The comments received during the public comment period largely pertain to short-term anorexiants. One comment specifically focused on the length of time that short-term anorexiants can be taken. The FDA guidelines state short-term anorexiants should be taken for “a short period of time.” The Board has determined that time to be 12 weeks based on its expertise and that timeframe is also common in other states. The Board’s goal in proposing the new and amended rules was to balance the needs of those Ohioans who utilize controlled substances for legitimate medical purposes against the need to limit controlled substance access in order to reduce diversion and addiction.

Upon review of the rule package, the CSI Office has determined that the rules satisfactorily meet the standards espoused by the CSI Office, and the purpose of the rules justifies the adverse impacts identified in the BIA.

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 State Medical Board should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.