

**MEMORANDUM**

TO: Sallie Debolt, State Medical Board of Ohio

FROM: Paula Steele, Regulatory Policy Advocate

DATE: September 17, 2014

RE: **CSI Review – Office Based Opioid Treatment** (OAC 4731-11-01 and 4731-11-12)

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 State Medical Board of Ohio rule package consists of one amended and one new proposed rule. The amended rule has been reviewed by the Board under the five-year review required by ORC 119.032. The proposed rules address office-based treatment of opioid addiction using federally-approved products. The rule package was filed with the CSI Office on March 31, 2014, and the comment period for the rule closed on April 14, 2014. One hundred eighty-one comments were received during the public comment period and as a result, the CSI Office helped facilitate additional outreach to stakeholders.

The proposed rules include definitions and treatment parameters for office-based opioid treatment (OBOT). The intent of the draft rules is to provide a balanced approach to access to treatment while curbing drug diversion opportunities of the medications being used to treat opiate-addicted patients. The proposed rules, particularly the new rule 4731-11-12 Office Based Opioid

Treatment, was the target of comments as the initially-proposed rule was seen to be overly prescriptive and created potential barriers to treatment access. For example, the original rule required that all urine toxicology tests be witnessed and that failed drug screens had to be confirmed through additional testing. These two provisions were described by commenters as unnecessary, impractical and required significant additional expense.

After reviewing the relatively consistent comments, the CSI Office facilitated a meeting with Board staff and interested parties from the Ohio Department of Mental Health & Addiction Services (MHAS). This discussion led to further follow-up and the Board reconvened an advisory panel of medical professionals with expertise in the treatment of addiction in order to consider input for potential rule changes that would help mitigate concerns over access to treatment. As a result of the comments and follow-up discussions, the Board made fifteen changes to the proposed rules and resubmitted the revised version to stakeholders and the CSI Office on August 26, 2014.

The CSI Office followed up with the advisory panel leader and determined that the changes proposed by the Board helped to improve the intended balance of the draft rules and that in general, the addiction treatment community was not opposed to the revised draft rules.

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 impact 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.

cc: Mark Hamlin, Lt. Governor's Office