

**MEMORANDUM**

TO: Holly Fischer, Ohio Board of Nursing

FROM: Danielle Dillard, Regulatory Policy Advocate

DATE: October 3, 2018

RE: **CSI Review – 2018 Technical Changes and Medication-Assisted Treatment (OAC 4723-5-08, 4723-7-04, 4723-7-05, 4723-7-06, 4723-7-10 and 4723-9-13)**

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 five amended rules and one new rule proposed by the Ohio Board of Nursing. The rule package was submitted to the CSI Office on September 7, 2018 and the public comment period was held open through September 21, 2018. Two comments were received during this time.

The five amended rules detail conditional approval of nursing programs, licensure of foreign-educated nurse graduates, registered nurse and practical nurse licensure by endorsement, and volunteer's certificates. The changes being made are nonsubstantive in nature, and are limited to correcting references and obsolete language, and making clarifying language changes.

Ohio Administrative Code (OAC) 4723-9-13 is the proposed new rule. The Board is required to promulgate rules that establish the standards and procedures nurse practitioners must follow when prescribing drugs for use in medication-assisted treatment. The need for regulation stems from the current opioid epidemic in Ohio, and reports of new "pill mills" for specifically approved

buprenorphine products, similar to the “pill mills” where prescription opiates such as OxyContin and Vicodin were prescribed for uses other than legitimate medical purposes. The new rule addresses detoxification, relapse prevention, patient assessment, individual planning, counseling and recovery supports, and diversion control. The Board notes that new rule will be consistent with the corresponding State Medical Board rules for physicians and physician assistants.

As part of the early stakeholder outreach process, the Board worked closely with the Ohio Department of Mental Health and Addiction Services and the State Medical Board to develop the new rule. The rule is drafted consistently with medication-assisted treatment rules proposed by the State Medical Board, which were reviewed by the Medical Board’s Physician Assistant Policy Committee and by interested parties, such as the Ohio State Medical Association. The rule concepts were discussed with the Board of Nursing’s Committee on Prescriptive Governance, and discussed with the Advisory Committee on Advanced Practice Registered Nursing (APRN Committee) at multiple meetings. The other rules in this package were also reviewed by the APRN Committee, and distributed to stakeholders and nursing associations for review. The Board made a number of language changes based on stakeholder feedback, and made revisions to the new medication-assisted treatment rule in tandem with the State Medical Board’s revision of its corresponding rule.

Two comments were received during the CSI comment period and one was substantive. The commenter asked about the level of detail in the new rule, and raised concerns over the practicality of implementing it in a timely manner. The Board noted that the level of detail in the rule is directly correlated with the requirements of the authorizing statute. Additionally, it noted that the rule is no more detailed than the corresponding rules promulgated by the Dental Board and State Medical Board.

The rules impact all individuals licensed by ORC Chapter 4723, nursing students, nursing education programs, and nurses who provide medication-assisted treatment. Nurses who wish to provide medication-assisted treatment for opioid addiction will have to complete eight hours of continuing education related to substance abuse and addiction. They will also incur costs for the time needed to perform the required assessments, formulate treatment plans, and comply with recordkeeping requirements.

The U.S. Drug Enforcement Administration (DEA) requires that nurses who intend to prescribe certain controlled substance medications for the purposes of maintenance and detoxification of opiate addiction receive a waiver from special registration requirements. There is no fee associated with applying for the waiver. In order to obtain the waiver, the nurse must complete twenty-four hours of initial training. This can be satisfied by completing both the eight-hour waiver course required for treatment of opioid use disorder that physicians take, plus an additional sixteen-hour course offered free of cost by the Substance Abuse and Mental Health Services Administration. The fee associated with the DEA registration is \$731 for the initial application and for every three-year renewal cycle.

The Board asserts that any adverse impact is justified because of the serious opioid epidemic in Ohio. Specifically approved buprenorphine products have been used successfully for the maintenance treatment for opioid dependence as part of a treatment plan that includes counseling and psychosocial support. However, specifically approved buprenorphine products are themselves opioids that are subject to abuse. Consequently, these rules serve to regulate the office-based maintenance treatment of persons with opiate addiction in a safe manner, while still providing access to that treatment in Ohio.

Recommendation

For the reasons explained above, this office does not have any recommendations regarding this rule package contingent on the Board's amendment as described above.

Conclusion

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