ACTION: Revised

DATE: 09/05/2017 12:36 PM

MEMORANDUM

TO: Cameron McNamee, Ohio Board of Pharmacy

FROM: Travis Butchello, Regulatory Policy Advocate

DATE: August 29, 2017

RE: **CSI Review – Pharmacy Technicians (OAC 4729:3-1-01, 4729:3-2-01 to 4729:3-2-05, 4729:3-3-01 to 4729:3-3-05, 4729:3-4-01, 4729:3-5-01, and 4729-4-01 through 4729-4-04)**

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This rule package consists of thirteen new and four rescinded rules proposed by the Ohio Board of Pharmacy as part of the statutory five-year rule review requirement. The rule package was submitted to the CSI Office on July 12, 2017 and the public comment period was held open through July 27, 2017. One hundred and three comments were received during this time. Responses to the comments were provided to the CSI Office on August 23, 2017.

The new rules implement regulations surrounding pharmacy technicians in Ohio. Specifically, the rules outline a technician's scope of permissible duties and practices, registration and education requirements, and continuing education standards. The Board has chosen to rescind Chapter 4729-4, which contained regulations surrounding pharmacy technicians and wishes to move those provisions to a new chapter and make requisite changes. The BIA states that the purpose for the rules is to ensure compliance with the ORC, which requires the Board of Pharmacy to adopt rules governing registration of pharmacy technicians and trainees.

As part of the early stakeholder outreach process, the Board submitted draft rules to the Board's rule review committee, which is made up of a variety stakeholders in the pharmaceutical industry throughout the state. During this process, the committee offered many suggestions and proposed changes. As a result, the Board chose to make numerous changes to the rules including clarifying the responsibilities of support personnel who are not required to be registered as pharmacy technicians, adding training and education programs that were non-employer based so that technicians will have more options and flexibility to comply with continuing education standards, and reducing the number of didactic, and practical experience training hours.

One hundred and three comments were received during the CSI public comment period. The majority of comments fell into one of three categories including, scope of duties technicians were allowed to perform, education and continuing education requirements, and registration requirements. Specifically, many commenters expressed concern about the scope of practice, including a suggestion to expand the scope of duties for technicians. The Board rejected CVS's suggestion to allow the delegation of dispensing functions to technicians but instead compromised to allow certified pharmacy technicians has to dispense refills as originally prescribed and give technicians the ability to accept verbal orders from prescribers to amend prescriptions provided there is direct supervision by a pharmacist. Other commenters expressed concern about the requirement of background checks for non-pharmacists who are allowed to handle medications. Specifically, the commenters suggested that support staff be given the authority, under supervision of the pharmacist, to accept purchased drugs for the pharmacy to inventory. The Board chose not to adopt these suggestions and outlined that it was essential for individuals who handle the drugs to have background checks, due to public safety concerns. Another group were concerned that technicians would not be able to leave their place of work for better opportunities because even if already certified, they would have to complete a subsequent training course because they were beginning a new place of employment. The Board responded that such notion was a misinterpretation of the rule and that technicians can move to new places of employment without needing to complete another training program to comply with the registration process. Lastly, some commenters stated that having 160 hours of didactic training hours and 320 hours of experiential training was excessive because it limits the ability of part-time employees to complete the requirements. In response, the Board chose to reduce the didactic hours to 80 and experiential hours to 120. The Board emphasized that while the 80 and 160 hours are under the national standard, the requirements help to limit the burden on technicians who need to complete the training all while ensuring pharmacy technician graduates possess the basic knowledge and experience to practice in most pharmacy settings.

The rules impact qualified pharmacy technicians, pharmacy technician trainees, registered pharmacy technicians, certified pharmacy technicians, terminal distributors of dangerous drugs, and pharmacists. The rules have a variety of adverse impacts on business, which include registration fees, costs of criminal records checks for applicants, license renewals, and pharmacy education trainings, classes, and programs. Specifically, the Board notes in the BIA that

registration costs for pharmacy technician trainees are $25 and $50 for certified and registered pharmacy technicians. In addition, costs of criminal records checks is approximately $24 plus a processing fee that may range from $5 to $40 respectively. The cost of a renewal for a two-year license is $50 for pharmacy and registered pharmacy technicians and the costs of trainings, classes, and programs for continuing education vary but registered pharmacy technicians will have to obtain 20 hours of continuing education every two years. Lastly, non-compliance with the rules may result in a disciplinary fee of $500 and/or revocation of a license. The BIA maintains that the regulatory intent of the rules justifies the impact on business because the regulations protect and promote public safety, are mandated by the ORC, and help ensure uniform licensing and training standards for pharmacy technicians throughout Ohio.

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