Common Sense Initiative

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

MEMORANDUM

TO: Cameron McNamee, State of Ohio Board of Pharmacy

FROM: Michael Bender, Business Advocate

DATE: August 31, 2023

RE: **CSI Review – Terminal and Drug Distributor Licensure (OAC 4729:5-2-02 and 4729:6-2-02)**

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

Analysis

This rule package consists of two new rules and two rescinded rules proposed by the State of Ohio Board of Pharmacy (Board) as part of the statutory five-year review process. This rule package was submitted to the CSI Office on July 25, 2023, and the public comment period was held open through August 17, 2023. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on July 25, 2023.

Ohio Administrative Code (OAC) 4729:5-2-02 and 4729:6-2-02 are rescinded and replaced by new rules with the same numbers. OAC 4729:5-2-02, the proposed new rule, provides for the initial licensure and licensure renewal of a terminal distributor of dangerous drugs. OAC 4729:6-2-02, the proposed new rule, provides for the initial licensure and licensure renewal of a distributor of dangerous drugs. The new rules differ from the rescinded versions by clarifying the initial licensure and renewal processes, removing duplicative provisions, and explaining what a terminal distributor or distributor needs to do with respect to licensure renewal when it experiences a change in either responsible person or description.

During early stakeholder outreach, the Board posted the rules to its website to solicit initial public comments from stakeholders. The Board did not receive any feedback. No comments were received during the CSI public comment period.

The business community impacted by the rules includes terminal distributors of dangerous drugs (e.g., pharmacies, hospitals, clinics, etc.) and drug distributors (e.g., wholesalers, manufacturers, etc.). The adverse impacts created by the rules include obtaining and renewing licensure. According to the Board, the renewal fees for terminal distributors are $320 for a Category II license and $440 for a Category III license. For drug distributors, the renewal fees are $1,900 for a Category II license and $2,000 for a Category III license. A $3.50 eLicense transaction fee is also included. The Board estimates that renewal, which is completed online, takes fifteen to forty-five minutes to complete. The Board points out that by permitting a change of business description application to be part of the license renewal process and authorizing any initial application submitted during the renewal period to have an expiration date, a licensee avoids duplicate licensure fees and avoids having to pay twice. The Board states that the adverse impacts to business are justified to implement statutory requirements and protect and promote public safety.

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 rules with the Joint Committee on Agency Rule Review.

Common Sense Initiative

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

MEMORANDUM

TO: Cameron McNamee, State of Ohio Board of Pharmacy

FROM: Michael Bender, Business Advocate

DATE: August 31, 2023

RE: **CSI Review – Pharmacist and Pharmacy Intern Licensure and Continuing Education (OAC 4729-6-01, 4729-6-02, 4729-6-03, 4729:1-2-01, 4729:1-2-02, 4729:1-2-03, 4729:1-2-04, 4729:1-2-05, 4729:1-2-06, 4729:1-2-07, 4729:1-2-08, 4729:1-5-01, 4729:1-5-02, 4729:1-5-03, 4729:2-1-01, 4729:2-2-01, 4729:2-2-02, 4729:2-2-03, 4729:2-2-04, 4729:2-2-05, 4729:2-2-06, 4729:2-2-07, 4729:2-2-08, 4729:2-2-09, and 4729:2-2-10)**

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

Analysis

This rule package consists of one new rule, fifteen amended rules, eight no-change rules, and two rescinded rules proposed by the State of Ohio Board of Pharmacy (Board) as part of the statutory five-year review process. This rule package was submitted to the CSI Office on July 25, 2023, and the public comment period was held open through August 17, 2023. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on July 25, 2023.

Ohio Administrative Code (OAC) 4729-6-01 specifies definitions pertaining to pharmacy continuing education (CE) providers. The rule is amended to remove a provision about CE units (CEUs) received prior to the effective date of the rule, as the provision no longer applies. OAC 4729-6-02 establishes

the minimum criteria that in-state providers of pharmacy jurisprudence CE must meet to obtain and maintain approval from the Board. The rule is amended to decrease the time period that providers are required to maintain certificates of completion from five year to four years and remove a provision about programs offered after the effective date of the rule that are less than one-tenth of a CEU, as the provision no longer applies. OAC 4729-6-03 establishes the minimum criteria that in-state providers of pharmacy CE for providing volunteer health care services must meet to obtain and maintain approval from the Board.

OAC 4729:1-2-01 provides for pharmacist licensure by examination. The rule is amended to update language, add clarifying language, allow the passing score to be determined by the National Association of Boards of Pharmacy (NABP) rather than list a specific score which had previously been seventy-five, reduce the amount of time available to submit the required fingerprints from twelve months after submitting an application to sixty days, and allow the Board to issue a limited or restricted license pursuant to ORC 4729.16. OAC 4729:1-2-02 provides for pharmacist licensure by reciprocity. The rule is amended to update language, permit a candidate to complete a no-cost law course developed by the Board, authorize the Board to require an applicant to complete the Multistate Pharmacy Jurisprudence Examination (MPJE) in lieu of completing the course, reduce the amount of time available to submit the required fingerprints from twelve months after submitting an application to six months, waive the requirements of ORC 4796.03(B)(1), establish the reciprocity fee pursuant to ORC 4796.03(F)(3) in addition to any transaction fee required by ORC 125.18, and allow the Board to issue a limited or restricted license pursuant to ORC 4729.16. OAC 4729:1-2-03 outlines the requirements for individuals applying to take the examinations for licensure as a pharmacist. The rule is amended to remove the requirement to submit a photograph to the Board, require an applicant to pay any transaction fee pursuant to ORC. 125.18, clarify that the certification establishing education equivalency submitted by an applicant must be provided by the NABP, and require an applicant to submit any other information or documentation as determined by the Board. OAC 4729:1-2-04 lists the passing scores for successful completion of the Test of English as a Foreign Language, Internet-based Test (TOEFL iBT).

OAC 4729:1-2-05 requires applicants for initial licensure as a pharmacist by examination or reciprocity to submit fingerprint impressions to the Bureau of Criminal Identification and Investigation (BCII) for a criminal records check consisting of both a BCII criminal check and a Federal Bureau of Investigation (FBI) criminal records check. OAC 4729:1-2-06 sets forth the requirements for pharmacists in the event of a change of name, address, or employment. The rule is amended to list a government-issued identification card and other documentation approved by the Board as options to accompany a notification of a name change, require a pharmacist who obtains a new wall certificate to promptly destroy the old certificate, and clarify that duplicate wall certificates may only be issued to pharmacists who have lost, misplaced, or damaged the original certificate. OAC 4729:1-2-07 is rescinded and replaced by a new rule with the same number, with changes made

to provide for reinstatement of an expired license. OAC 4729:1-2-07, the proposed new rule, provides for pharmacist licensure renewal. OAC 4729:1-2-08 provides for the renewal of expired pharmacist licenses by active-duty military members and their spouses. OAC 4729:1-5-01 specifies definitions pertaining to pharmacy CE. The rule is amended to add two certifications that are recognized by the Board for CE purposes. OAC 4729:1-5-02 contains the CE requirements for pharmacists. The rule is amended to reduce the number of required CE contact hours from forty to thirty, exempt newly licensed pharmacists from having to complete CE within the first two years of licensure, and clarify that audits of licensees will be determined by the Board. OAC 4729:1-5-03 provides for the pharmacy CE of active-duty military members and their spouses. The rule is amended to make a grammatical correction.

OAC 4729:2-1-01 specifies definitions pertaining to pharmacy interns. The rule is amended to clarify that a pharmacist may only supervise up to two interns at a time or up to six if providing immunizations only. OAC 4729:2-2-01 sets forth the criteria for licensure as a pharmacy intern. The rule is amended to update language. OAC 4729:2-2-02 provides for the application for licensure as a pharmacy intern. The rule is amended to remove the requirement to submit a photograph to the Board, require an applicant to pay any transaction fee pursuant to ORC. 125.18, clarify that an applicant may be licensed when the Board receives the results of a criminal records check, waive the requirements of ORC 4796.03(B)(1), clarify that the certification establishing education equivalency submitted by an applicant must be provided by the NABP, permit licensure by reciprocity, require an applicant to submit any other information or documentation as determined by the Board, and allow the Board to issue a limited or restricted license pursuant to ORC 4729.16. OAC 4729:2-2-03 requires applicants for initial licensure as a pharmacy intern to submit fingerprint impressions to the BCII for a criminal records check consisting of both a BCII criminal check and an FBI criminal records check. OAC 4729:2-2-04 provides for pharmacy intern licensure renewal and expiration. The rule is amended to update language, incorporate the licensure renewal process provisions from proposed rescinded rule OAC 4729:2-2-09, authorize the Board to approve license extensions, and require the Board to inactivate an intern license upon notification that the intern is no longer enrolled in a school of pharmacy. OAC 4729:2-2-05 provides for the satisfactory completion of the pharmacy internship credit requirement.

OAC 4729:2-2-06 requires pharmacy interns to submit a completed statement of preceptor if there is a change in preceptor or employment site and requires the use of a practical experience affidavit form to submit evidence of practical experience for internship credit earned outside of the intern's pharmacy school academic program. The rule is amended to add clarifying language and require practical experience affidavits to be submitted no later than one year after credit is earned rather than by March 1st of the following year. OAC 4729:2-2-07 lists the passing scores for successful completion of the TOEFL iBT. OAC 4729:2-2-08 sets forth the requirements for pharmacy interns in the event of a change of name, address, or employment. The rule is amended to list a government-

issued identification card and other documentation approved by the Board as options to accompany a notification of a name change. OAC 4729:2-2-09 is rescinded, with its contents proposed to be moved to OAC 4729:2-2-04. OAC 4729:2-2-10 provides for the renewal of expired pharmacy intern licenses by active-duty military members and their spouses.

During early stakeholder outreach, the Board posted the rules to its website to solicit initial public comments from stakeholders. The Board received comments from three pharmacists. The first advocated for the addition of the -07 and -08 Universal Activity Numbers assigned by the Accreditation Council for Pharmacy Education alongside the existing -05 compounding designator required in the rules, but the Board argued that the original intent of a patient safety/medication error prevention focus would be lost by adding two more designations and did not incorporate this suggestion. The second pharmacist asked the Board to allow internship credit to be awarded through pharmacy school academic programs, which the Board agreed to. The third pharmacist asserted that the MPJE offered no significant information for test takers of colleges of pharmacy to assess performance. The Board replied that it was exploring other options but emphasized that the MPJE is the national standard currently used by most states to assess pharmacy law competency. No comments were received during the CSI public comment period, although the Board made some technical corrections.

The business community impacted by the rules includes providers of CE, pharmacists, pharmacy interns, and applicants for licensure as pharmacists or pharmacy interns. The adverse impacts created by the rules include obtaining and maintaining approval from the Board, obtaining licensure, renewing licensure, continuing education, submitting information, recordkeeping, test-taking, undergoing a criminal records check, and paying fees. The Board notes that there are fees specifically for taking the North American Pharmacist Licensure Examination ($485) and the MPJE ($200), reciprocity for pharmacists ($337.50), a new wall certificate ($22.50), submitting a pharmacy intern application ($30.00), licensure renewal ($250 plus a $3.50 eLicense transaction fee), lapsed licensure renewal ($337.50), and obtaining a criminal records check ($61.70 combined for the BCII and FBI checks). The Board estimates that it takes five minutes for an intern to notify the Board that he or she is no longer enrolled in a school of pharmacy, five to ten minutes to complete the statement of preceptor form, fifteen to thirty minutes for active-duty military members or their spouses to submit required documentation to the Board, and thirty to sixty minutes for an applicant to submit a request to the Board to obtain practical experience at a site other than a pharmacy. The Board points out that the retention time for maintaining certificate of completion is reduced from five years to four, the number of required CE hours is reduced from forty to thirty, and pharmacists who obtain an initial license will not have to meet CE requirements for the first renewal cycle. The Board states that the adverse impacts to business are justified to implement statutory requirements and protect and promote public safety.

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 rules with the Joint Committee on Agency Rule Review.

Common Sense Initiative

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

MEMORANDUM

TO: Cameron McNamee, State of Ohio Board of Pharmacy

FROM: Michael Bender, Business Advocate

DATE: August 31, 2023

RE: **CSI Review – Pharmacy Technicians (OAC 4729:3-2-01, 4729:3-3-02, 4729:3-3-03, and 4729:7-2-03)**

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

Analysis

This rule package consists of four amended rules proposed by the State of Ohio Board of Pharmacy (Board) as part of the statutory five-year review process. This rule package was submitted to the CSI Office on July 25, 2023, and the public comment period was held open through August 17, 2023. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on July 25, 2023.

Ohio Administrative Code (OAC) 4729:3-2-01 sets forth the registration procedures for pharmacy technician trainees, registered pharmacy technicians, and certified pharmacy technicians. The rule is amended to add clarifying language, update language and citations, incorporate statutory transaction fees, allow licensure reciprocity, extend the time period for active employment in another state that may be considered for compliance purposes from within the previous three years to within the previous five years, and extend the time period for a trainee registration from one year to eighteen months. OAC 4729:3-3-02 establishes the standards for pharmacy technician training programs to ensure that program graduates have the basic knowledge and experience in general pharmacy to

practice in most pharmacy settings. The rule is amended to add a citation, clarify who is responsible for providing documentation of a successful training program, require a terminal distributor of dangerous drugs providing employer-based training at more than one licensed location to develop and implement written policies and procedures related to compliance with the rule, and require technician trainees that engage in sterile and non-sterile compounding to comply with applicable United States Pharmacopeia (USP) training requirements. OAC 4729:3-3-03 specifies certain requirements and allowable actions for registered pharmacy technicians. The rule is amended to add a citation, permit registered pharmacy technicians to perform sterile compounding on the condition that the specified training is completed, and require registered pharmacy technicians that engage in non-sterile compounding to comply with applicable USP training requirements. OAC 4729:7-2-03 provides for the compounding of drugs in a pharmacy. The rule is amended to allow registered pharmacy technicians to engage in sterile drug compounding.

During early stakeholder outreach, the Board posted the rules to its website to solicit initial public comments from stakeholders. The Board received one comment expressing concerns with registered pharmacy technicians being able to perform sterile compounding and suggesting that registered pharmacy technicians be allowed to perform sterile compounding on a limited basis. The Board incorporated this suggestion into the rules. No comments were received during the CSI public comment period, although the Board made a technical correction.

The business community impacted by the rules includes pharmacies and pharmacy technicians. The adverse impacts created by the rules include obtaining registration, going through proper training, adherence to national compounding standards, and reporting information to the Board. According to the Board, the cost for reciprocity is $25.00 and $50.00 for registered and certified technicians, respectively, with the application taking thirty minutes to an hour to complete. Employers who develop an internal training program will experience increased administrative and other compliance costs, while those who engage in drug compounding will experience increased training costs. Similarly, terminal distributors who permit registered pharmacy technicians to engage in sterile compounding will experience increased administrative costs. Furthermore, the costs to a pharmacy of adhering to national drug compounding standards may cost anywhere from thousands of dollars to more than $100,000, depending on the type of compounding it performs. The Board, citing Pharmacy Times, notes that obtaining the necessary personal protective equipment and achieving facility improvements may respectively cost $5,000 and up to $50,000, with any facility changes requiring about twelve to eighteen months to complete. Additionally, reporting information to the Board online is expected to take thirty minutes to an hour. The Board points out that the regulatory burden of the rules is reduced by extending the time period for a trainee registration, removing the requirement for a program director to sign off on trainee documentation, and permitting registered pharmacy technicians to perform sterile compounding for training purposes. The Board states that the adverse impacts to business are justified to implement statutory requirements and protect and

promote public safety.

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 rules with the Joint Committee on Agency Rule Review.