10/16/19

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

Amend:

- 4729:3-3-04: Establishes the activities certified pharmacy technicians may perform. The rule is amended to remove the requirement of documented positive identification by the sending certified pharmacist technicians and the pharmacist on duty when authorizing the transfer of the prescription copy.

Comments on the proposed rules will be accepted until close of business on October 31, 2019. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Cameron McNamee
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Regulation/Package Title (a general description of the rules' substantive content):

Certified pharmacy technicians

Rule Number(s): 4729:3-3-04

Date of Submission for CSI Review: 10/16/19

Public Comment Period End Date: 10/31/19

Rule Type/Number of Rules:

New/___ rules

Amended/__1__rules (FYR? _N_)

No Change/____ rules (FYR? ___)

Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing

regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

Requires completion of compounding training before engaging in drug compounding. Requires completion of hazardous drug handling training before handling hazardous drugs.

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

Violation of the rule may result in administrative discipline for a licensee or registrant. Discipline might include reprimand, suspension of a license, required course work, monetary penalty and/or revocation/denial of a license.

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   - 4729:3-3-04: Establishes the activities certified pharmacy technicians may perform. The rule is amended to remove the requirement of documented positive identification by the sending certified pharmacist technicians and the pharmacist on duty when authorizing the transfer of the prescription copy. NOTE: This requirements has been removed for pharmacy interns see proposed rule 4729:5-5-10.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The proposed rules are authorized by sections 4729.26, 4729.10 and 4729.94 of the Ohio Revised Code.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?** ***If yes, please briefly explain the source and substance of the federal requirement.***

These rules do not implement a federal requirement.

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

This rule package exceeds federal requirements because the regulation of the practice of pharmacy, including pharmacy technicians, has traditionally been done at the state level by legislatively created state boards of pharmacy.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

Section 4729.94 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules governing registration of registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulation will be measured by having a rule written in plain language, Licensee/registrant compliance with the rule, and minimal questions from licensees/registrants regarding the provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.
If applicable, please include the date and medium by which the stakeholders were initially contacted.

The rule in this package was reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from a number of practice settings, is responsible for reviewing and approving all rules prior to their legislatively mandated five-year review date.

Prior to filing with CSI, the rule was also reviewed and approved by the Board of Pharmacy.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Stakeholders had no comments on the proposed amendment to the rule.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data was not used to develop or review this rule.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the regulation and oversight of pharmacy technicians, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. Did the Agency specifically consider a performance-based regulation? Please explain.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to a performance based regulation.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rule to ensure that the regulation does not duplicate another State of Ohio Board of Pharmacy regulation.

15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rule will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Additionally, the Board has a pharmacy technician page on its website that includes a number of frequently asked questions regarding pharmacy technician practice. The guidance documents on that page will also be updated accordingly.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and quarterly webinars from the Director of Policy and Communications and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community; and

The rule package impacts the following:

- Certified pharmacy technicians.

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

Violation of the rule may result in administrative discipline for a licensee or registrant. Discipline might include reprimand, suspension of a license, required course work, monetary penalty and/or revocation/denial of a license.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a

"representative business." Please include the source for your information/estimated impact.

Amend:

- 4729:3-3-04: Establishes the activities certified pharmacy technicians may perform. The rule is amended to remove the requirement of documented positive identification by the sending certified pharmacist technicians and the pharmacist on duty when authorizing the transfer of the prescription copy. This change will reduce administrative costs of compliance associated with the rule.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform training standards and oversight of pharmacy technicians.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy by pharmacists and pharmacy interns is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, the Board has a pharmacy technician page on its website that includes a number of frequently asked questions regarding pharmacy technician practice. The guidance documents on that page will also be updated accordingly.

4729:3-3-04 Certified pharmacy technicians. (AMEND)

(A) As used in this rule, "positive identification" has the same meaning as in rule 4729:5-5-01 of the Administrative Code.

(B) A certified pharmacy technician shall wear a name tag or badge which contains the designation "Certified Pharmacy Technician." The required designation may be added to an existing name tag or badge. The name tag or badge and the required designation shall contain lettering of a legible size.

(C) A certified pharmacy technician may, under the direct supervision of a pharmacist, engage in the following activities at a location licensed as a terminal distributor of dangerous drugs to the extent that the activities do not require the exercise of professional judgment:

(1) Accepting new written, faxed or electronic prescription orders from a prescriber or a prescriber's agent. New verbal prescription orders from a prescriber or a prescriber's agent for non-controlled drugs may be accepted pursuant to paragraph (C)(13) of this rule.

(2) Entering information into and retrieving information from a database or patient profile.

(3) Preparing and affixing labels.

(4) Stocking dangerous drugs and retrieving those drugs from inventory.

(5) Counting and pouring dangerous drugs into containers.

(6) Placing dangerous drugs into containers prior to dispensing by a pharmacist.

(7) Non-sterile drug compounding in accordance with the required training in paragraph (D) of this rule.

(8) Sterile drug compounding in accordance with the required training in paragraph (E) of this rule.

(9) Packaging and selling a dangerous drug to a patient or patient representative.

(10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner.

(11) Stocking automated drug dispensing units, floor stock and crash carts at a location licensed as a terminal distributor of dangerous drugs.

(a) Notwithstanding the definition of direct supervision in rule 4729:3-1-01 of the Administrative Code, a certified pharmacy technician may stock an automated drug dispensing unit and floor

stock at a location licensed as a terminal distributor of dangerous drugs if a pharmacist is not physically present at the licensed location and all of the following apply:

(i) A pharmacist is readily available to answer questions of the certified pharmacy technician;

(ii) A pharmacist is responsible for conducting routine verifications of the activities of the certified pharmacy technician to prevent the diversion of dangerous drugs;

(iii) A pharmacist is fully responsible for all activities conducted by the certified pharmacy technician at the licensed location.

(12) Requesting refill authorizations for dangerous drugs from a prescriber or prescriber's agent, so long as there is no change from the original prescription;

(13) Accepting new verbal prescription orders, including refill authorizations, for non-controlled drugs from a prescriber or a prescriber's agent pursuant to all of the following:

(a) The pharmacist on duty who is supervising the activity of the certified pharmacy technician will determine if the technician is competent to receive a verbal order.

(b) The pharmacist on duty who is supervising the activity of the certified pharmacy technician is responsible for the accuracy of a prescription order received by a technician.

(c) The pharmacist on duty must be immediately available to answer questions or discuss the prescription order received by a certified pharmacy technician.

(d) The certified pharmacy technician may not receive a prescription order for a controlled substance.

(e) If applicable, the certified pharmacy technician receiving a prescription order must document the full name of the prescriber's agent.

(f) The receiving certified pharmacy technician shall immediately reduce the prescription order to writing and shall review the prescription with the pharmacist on duty.

(g) Prior to dispensing, positive identification of the receiving certified pharmacy technician and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the prescription.

(h) The certified pharmacy technician and the pharmacist on duty must meet all other applicable rules for the receipt of new verbal prescription orders pursuant to agency 4729 of the Administrative Code.

(14) Send or receive copies of non-controlled prescriptions pursuant to all of the following:

(a) The pharmacist on duty who is supervising the activity of the certified pharmacy technician will determine if the technician is competent to send or receive a prescription copy.

(b) The pharmacist on duty who is supervising the activity of the certified pharmacy technician is responsible for the accuracy of a prescription copy that is sent or received by a technician.

(c) The pharmacist on duty must be immediately available to answer questions or discuss the prescription copy that is sent or received by a certified pharmacy technician.

(d) The certified pharmacy technician may not send or receive a prescription copy for a controlled substance.

(e) The pharmacist or certified pharmacy technician receiving a prescription copy from a certified pharmacy technician must document the full names of the sending technician and the technician's supervising pharmacist. The receiving technician shall immediately reduce the prescription copy to writing and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the certified pharmacy technician and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the copy.

(f) The pharmacist or certified pharmacy technician sending a prescription copy to a certified technician must document the full names of the receiving technician and the technician's supervising pharmacist. ~~There must be documented positive identification of the sending certified pharmacy technician and the pharmacist on duty who authorized the transfer of the prescription copy.~~

(g) The certified technician and the pharmacist on duty must meet all other applicable rules for the transfer of a prescription copy pursuant agency 4729 of the Administrative Code.

(15) Contacting a prescriber or prescriber's agent to obtain clarification for a prescription order if the clarification does not require the exercise of professional judgment.

(16) Performing diagnostic laboratory testing pursuant to agency 4729 of the Administrative Code.

(D) In order to perform non-sterile drug compounding, a certified pharmacy technician shall complete the following training requirements prior to compounding non-sterile preparations:

(1) Training shall comply with the requirements set forth in the United States pharmacopeia chapter <795>.

(2) Non-sterile drug compounding training shall be obtained through completion of a site-specific, structured on-the-job didactic and experiential training program and shall not be transferable to another practice site, except between practice sites under common ownership and control.

(3) When the responsible person or a pharmacist designated by the responsible person is satisfied with the employee's knowledge and proficiency, the responsible person or the responsible person's designee will sign the documentation records to show that the employee was appropriately trained in accordance with this rule.

(4) Ensuring certified pharmacy technicians are properly trained shall be the responsibility of the terminal distributor of dangerous drugs and the licensee's responsible person.

(5) All training requirements set forth in this paragraph shall be appropriately documented and made readily retrievable for immediate inspection by an agent of the state board of pharmacy. Documentation shall be maintained by the terminal distributor of dangerous drugs for a minimum of three years.

(E) In order to perform sterile drug compounding, a certified pharmacy technician shall complete the following training requirements prior to compounding sterile preparations:

(1) Training shall comply with the requirements set forth in the United States pharmacopeia chapter <797>.

(2) Sterile drug compounding training shall be obtained through completion of a site-specific, structured on-the-job didactic and experiential training program and shall not be transferable to another practice site, except between practice sites under common ownership and control.

(3) When the responsible person or a pharmacist designated by the responsible person is satisfied with the employee's knowledge and proficiency, the responsible person or the responsible person's designee will sign the documentation records to show that the employee was appropriately trained in accordance with this rule.

(4) Ensuring certified pharmacy technicians are properly trained shall be the responsibility of the terminal distributor of dangerous drugs and the licensee's responsible person.

(5) All training requirements set forth in this paragraph shall be appropriately documented and made readily retrievable for immediate inspection by an agent of the state board of pharmacy. Documentation shall be maintained by the terminal distributor of dangerous drugs for a minimum of three years.

(F) A terminal distributor of dangerous drugs and the licensee's responsible person shall be responsible for the implementation of policies and procedures for additional training appropriate to duties and responsibilities performed by a certified pharmacy technician as well as an ongoing quality assurance plan to ensure competency.