

OHIO GENERAL ASSEMBLY
JOINT COMMITTEE ON AGENCY RULE REVIEW

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R.C. 121.93 Required Report

- 1) **Date: 3/30/2023**
- 2) **Agency: State of Ohio Board of Pharmacy**
- 3) **Agency Contact**
 - a) Name: Cameron McNamee
 - b) Email: cameron.mcnamee@pharmacy.ohio.gov
 - c) Phone: 614-466-7322
- 4) Provide the number of operations reviews that your agency completed during the governor's recently expired term. **During the Governor's recently expired term, the Board conducted a complete review and reorganization of its administrative rule chapters. As part of this comprehensive review and reorganization, Board of Pharmacy rules were reviewed at least once to identify any principles of law or policies listed in ORC 121.93(A).**
- 5) List any principles of law or policies described in [R.C. 121.93\(A\)](#) that your agency identified in your operations review(s). **The Board identified the following law or policies that needed to be incorporated into Administrative Rule:**
 - **OAC 4729:5-9-03.4 – This rule incorporated a long-standing Board policy regarding electronic timeouts for automated drug storage systems. The previous rule had a security requirement but did not specify the timeout requirements. Therefore, this policy was incorporated into the rule.**
 - **OAC 4729:5-5-20 – This rule built on a long-standing Board policy of permitting pharmacists to conduct remote order entry in outpatient settings. Therefore, the specifics of that policy were incorporated into a standalone rule along with improvements made by licensees impacted by the policy.**
 - **OAC 4729:5-9-02.14 – This rule built on a long-standing Board policy of permitting pharmacists to conduct remote order entry in institutional settings. Therefore, the specifics of that policy were incorporated into a standalone rule along with improvements made by licensees impacted by the policy.**
 - **Temperature Monitoring Requirements (multiple rules) – Generally, the Board had an inspection policy requiring regular temperature monitoring for sites storing drugs.**

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During the review process, the Board implemented standardized requirements for temperature monitoring across all license types.

- **OAC 4729:5-5-23** – A previous version of this rule did not specify certain alarm testing requirements that were conducted during inspections. The rule was updated to include specific requirements for the testing of outpatient pharmacy security systems.
- **OAC 4729:5-9-02.2** – A previous version of this rule did not specify certain alarm testing requirements that were conducted during inspections. The rule was updated to include specific requirements for the testing of inpatient pharmacy security systems.
- **OAC 4729:5-3-17** – A previous version of this rule had general standards for approval of automated pharmacy systems but did not include any accuracy standards. Those standards were governed by internal Board policies. During the Board’s rule reorganization, this rule was updated to include the specific standards for Board approval of an automated pharmacy system.
- **OAC 4729:5-3-12** – This rule was previously governed by a Joint Regulatory Statement between the Medical, Nursing and Pharmacy Boards on the appropriate use of protocols and pre-printed orders for drug administration. During the Board’s rule reorganization, it reached out to each respective agency to craft an administrative rule that incorporated the policy.
- **OAC 4729:3-3-03** – This rule incorporates the scope of practice for registered pharmacy technicians. To maintain pharmacy operations during the COVID-19 pandemic, the Board expanded some of the duties of registered pharmacy technicians to perform additional duties via policy. The Board is in the process of updating its scope of practice rule to incorporate these changes authorized during the pandemic.
- **OAC 4729:4-1-09** – This rule incorporates the standard terms and conditions for someone whose license has been suspended by the Board. These requirements were previously part of the Board’s probation policy.
- **OAC 4729:6-3-04** – This rule incorporates a license verification policy for those entities that are exempted from Board of Pharmacy licensure [see OAC 4729:6-3-04(D)].
- **OAC 3796:6-3-02** – This rule incorporates standards from the Board’s Request for Application for medical marijuana dispensary licenses. Specifically, the rule incorporates the standards from the RFA related to signage placement, enclosed delivery bays, and vault specifications.
- **OAC 3796:6-3-01** – This rule incorporates a COVID-19 policy that permitted dispensaries to issue their own employee identification badges.
- **OAC 3796:8-2-04** – This rule incorporates a Board policy that adjusted the amount medical marijuana plant material that constitutes a 90-day supply.

6) Describe your agency’s considerations regarding the identified principles of law or policies under [R.C. 121.93\(B\)](#).

- **OAC 4729:5-9-03.4** – This rule incorporated a long-standing Board policy regarding electronic timeouts for automated drug storage systems. The previous rule had a security requirement but did not specify the timeout requirements. Therefore, this

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specific policy was incorporated into the rule. [Assert the general and uniform operation of the principle of law or policy]

- OAC 4729:5-5-20 – This rule built on a long-standing Board policy of permitting pharmacists to conduct remote order entry in outpatient settings. Therefore, the specifics of that policy were incorporated into a standalone rule along with improvements made by licensees impacted by the policy. [Enable greater participation by persons specifically affected by the principle of law or policy in the improvement and further development of the principle of law or policy]
- OAC 4729:5-9-02.14 – This rule built on a long-standing Board policy of permitting pharmacists to conduct remote order entry in institutional settings. Therefore, the specifics of that policy were incorporated into a standalone rule along with improvements made by licensees impacted by the policy. [Enable greater participation by persons specifically affected by the principle of law or policy in the improvement and further development of the principle of law or policy]
- Temperature Monitoring Requirements (multiple rules) – Generally, the Board had a policy requiring regular temperature monitoring for sites storing drugs. During the review process, the Board implemented clear requirements for temperature monitoring across all license types. [Assert the general and uniform operation of the principle of law or policy]
- OAC 4729:5-5-23 – Previous iterations of this rule did not specify certain alarm testing requirements that were conducted during inspections. The rule was updated to include specific requirements for the testing of outpatient pharmacy security systems. [Assert the general and uniform operation of the principle of law or policy]
- OAC 4729:5-9-02.2 – Previous iterations of this rule did not specify certain alarm testing requirements that were conducted during inspections. The rule was updated to include specific requirements for the testing of inpatient pharmacy security systems. [Assert the general and uniform operation of the principle of law or policy]
- OAC 4729:5-3-17 – A previous version of this rule had general standards for approval of automated pharmacy systems but did not include any accuracy standards in rule. Those standards were governed by internal Board policies. During the Board’s rule reorganization, this rule was updated to include the specific standards for Board approval of an automated pharmacy system. [Enable the principle of law or policy to be better known in advance of its application]
- OAC 4729:5-3-12 – This rule was previously governed by a Joint Regulatory Statement between the Medical, Nursing and Pharmacy Boards on the appropriate use of protocols and pre-printed orders for drug administration. During the Board’s rule reorganization, it reached out to each respective agency to craft an administrative rule that incorporated the policy. [Assert the general and uniform operation of the principle of law or policy]
- OAC 4729:3-3-03 – This rule incorporates the scope of practice for registered pharmacy technicians. To maintain pharmacy operations during the COVID-19 pandemic, the Board expanded some of the duties of registered pharmacy technicians to perform additional duties via policy. The Board is in the process of updating its

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scope of practice rule to incorporate these changes authorized during the pandemic.
[Assert the general and uniform operation of the principle of law or policy]

- OAC 4729:4-1-09 – This rule incorporates the standard terms and conditions for someone whose license has been suspended by the Board. These requirements were previously part of the Board’s probation policy. [Assert the general and uniform operation of the principle of law or policy]
- OAC 4729:6-3-04 – This rule incorporates a license verification policy for those entities that are exempted from Board of Pharmacy licensure [see OAC 4729:6-3-04(D)]. [Assert the general and uniform operation of the principle of law or policy]
- OAC 3796:6-3-02 – This rule incorporates standards from the Board’s Request for Application for medical marijuana dispensary licenses. Specifically, the rule incorporates the standards from the RFA related to signage placement, enclosed delivery bay, and vault specifications. [Assert the general and uniform operation of the principle of law or policy]
- OAC 3796:6-3-01 – This rule incorporates a COVID-19 policy that permitted dispensaries to issue their own employee identification badges. [Enable greater participation by persons specifically affected by the principle of law or policy in the improvement and further development of the principle of law or policy]
- OAC 3796:8-2-04 – This rule incorporates a Board policy that adjusted the amount medical marijuana plant material that constitutes a 90-day supply. [Enable greater participation by persons specifically affected by the principle of law or policy in the improvement and further development of the principle of law or policy]

7) List any principles of law or policies for which your agency determined rulemaking is indicated or for which your agency has commenced the rulemaking process under [R.C. 121.93\(C\)](#).

- OAC 4729:5-9-03.4 – The policy has already been incorporated into the rule effective 2/1/22.
- OAC 4729:5-5-20 – The policy has already been incorporated into the rule effective 11/30/22.
- OAC 4729:5-9-02.14 – The policy has already been incorporated into the rule effective 11/30/22.
- Temperature Monitoring Requirements (multiple rules) – The policy has already been incorporated into the rules in 2020-2021.
- OAC 4729:5-5-23 – The policy has already been incorporated into the rule effective 12/1/20.
- OAC 4729:5-9-02.2 – The policy has already been incorporated into the rule effective 2/1/22.
- OAC 4729:5-3-17 – The policy has already been incorporated into the rule effective 6/4/21.
- OAC 4729:5-3-12 – This policy has already been incorporated into the rule effective 3/1/20.

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- **OAC 4729:3-3-03** – The rule incorporating this policy is currently under internal agency review and will go out for initial public comment next month. The goal is to have the rule finalized by the end of this calendar year.
- **OAC 4729:4-1-09** – This policy has already been incorporated into the rule effective 2/4/21.
- **OAC 4729:6-3-04** – This policy has already been incorporated into the rule effective 3/1/19.
- **OAC 3796:6-3-02** – The rule incorporating this policy is awaiting final filing with JCARR. The Board expects the rule to be final filed in April 2023.
- **OAC 3796:8-2-04** – This policy has already been incorporated into the rule effective 2/14/22.