# Ohio Administrative Code

## Rule 4729:5-3-20 Pharmacy pilot or research projects.

Effective: March 11, 2022

(A) The purpose of this rule is to specify the process and procedures to be followed when a licensee petitions for approval of a pilot or research project for innovative system applications in the practice of pharmacy that are not currently permitted under agency 4729 of the Administrative Code. In reviewing projects, the board shall consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes.

(B) A project shall not expand the definition of the practice of pharmacy as set forth in Chapter 4729. of the Revised Code and shall not apply to licensees regulated under Chapter 3796. of the Revised Code.

(C) Approval of a project by the board may include the grant of a limited exception to or a waiver of rules adopted under Chapter 4729. of the Revised Code. Project approval, including limited exception to or waiver of board rules, shall initially be for a specified period of time not exceeding twenty-four months from commencement of the project.

(D) Following the completion of the project period, the board may do any of the following based upon a review of the final project report submitted in accordance with paragraph (I) of this rule and any other factors or information the board deems necessary:

(1) Refuse to extend or renew the project;

(2) Approve the extension or renewal of a project following consideration of a petition that clearly identifies the need for extension and must include a report similar to the final project report, which should describe and explain any proposed changes to the originally approved and implemented project, and that justifies the need for extending or renewing the term of the project; or

(3) Approve the project in perpetuity following a consideration of a petition that clearly identifies and justifies the need to continue the project indefinitely.

(E) A licensee who wishes the board to consider approval of a project shall submit to the board a petition for approval that contains at least the following information:

(1) Responsible pharmacist. Name, address, telephone number, and pharmacist license number of each pharmacist responsible for overseeing the project.

(2) Location of project. Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy's terminal distributor of dangerous drugs license number where the proposed project will be conducted.

(3) Project summary. A detailed summary of the proposed project that includes at least the following information:

(a) The goals, hypothesis, and objectives of the proposed project.

(b) A full explanation of the project and how it will be conducted.

(c) The time frame for the project including the proposed start date and length of the project. The time frame may not exceed eighteen months from the proposed start date of the project.

(d) Background information or literature review to support the proposed project.

(e) The rule or rules to be waived in order to implement the project, an explanation of why such a waiver would not be a detriment to the public, to include procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver, and a request to waive the rule or rules.

(F) Projects submitted shall be reviewed as follows:

(1) Staff review. Upon receipt of a petition for approval of a project, board staff shall initially review the petition. If the petition is incomplete or fails to meet the board's outlined purpose, staff shall return the petition to the requestor with a letter explaining the reason the petition is being returned. A

petition that has been returned pursuant to this paragraph may be amended or supplemented as necessary and submitted for reconsideration. A petition that is deemed appropriate and complete shall move on the board member review process.

(2) Board member review. After initial staff review, two members of the board, appointed by the board president, shall be provided the petition and any additional materials. Board members shall conduct a review, in consultation with appropriate staff, and make a recommendation to the full board. Board members conducting a review may request additional documentation and information from the petitioner as part of this review process.

(3) Board review. Following the board member review, the board shall consider the project request at a regularly scheduled meeting of the board. Upon review, the board shall either approve or deny the petition. The board shall not approve any such project if such proposal might jeopardize public health or welfare. If the board approves the petition, the approval:

(a) Shall be specific for the project requested, with any modifications the Board deems necessary for patient safety;

(b) Shall approve the project for a specific time period; and

(c) May include conditions or qualifications applicable to the project, including limited waivers of applicable/related rules.

(G) The project site and project documentation shall be available for inspection and review by the board or its representative(s) at any time during the approval or denial processes and, if a project is approved, throughout the approved term of the project.

(H) Project documentation shall be maintained in a readily retrievable manner and available for inspection, review, and copying by the board or its representative for at least three years following completion or termination of the project.

(I) The pharmacist responsible for overseeing a project shall be responsible for submitting to the board any reports required as a condition of a project, including the final project report.

(1) The final project report shall include a written summary of the results of the project and the conclusions drawn from those results. The final project report shall be submitted to the board within ninety days after completion or termination of the project.

(2) The board shall review any required report regarding the progress of a project and the final project report at a regularly scheduled meeting of the board.

(J) The board may rescind approval and terminate projects, including those it has approved in perpetuity, pursuant to the following:

(1) If the board deems the project does not the comply with the requirements of this rule or the conditions of its approval, the board shall provide notice to the pharmacist responsible for the project indicating the projects approval has been rescinded. The notice shall provide sixty days for the pharmacist to address any deficiencies prior to the termination of the project. If the deficiencies cited in the notice are addressed, the board may reinstate the project prior to its proposed termination date.

(2) If the board has reasonable cause to believe the project poses a threat of immediate or serious harm to the public, the board shall provide notice to the pharmacist responsible for the project indicating the projects approval has been rescinded. The termination of the project shall take effect immediately.

(K) The petitioner and/or projects responsible person may terminate the project earlier than requested but shall provide notice within three business days of termination and a final project report to the board to include an explanation of why the project was terminated early. Upon either recission of approval or early project termination, any waivers granted will be immediately revoked and the licensee will be required to adhere to those rules that had been excepted or waived.

(L) All documents pertaining to the application, project, and reports are considered a public record under section 149.43 of the Revised Code and will be provided upon request, without notice to the projects petitioners and/or responsible person. Petitioners asserting that some or all of an application contains information exempt from disclosure under Ohio law shall comply with the following:

(1) Submit a memorandum identifying the content not subject to disclosure under section 149.43 of the Revised Code, including supporting legal authority for each assertion.

(2) Submit a redacted version of the materials that the applicant agrees may be released without prior notice to the applicant.

(M) By submitting the application, the petitioner understands, acknowledges, and agrees to all of the following:

(1) The board may independently assess the merits of any public records exception claims made by the petitioner.

(2) The board may reject a claim that information in an application is trade secret or a security or infrastructure record if it determines that the petitioner has not established that the content in question meets a delineated exception to public disclosure under Ohio law, including the use of generic language encompassing substantial portions of the application submission or simple assertions of a document containing information exempt from public disclosure, without substantive explanation of the basis.

(3) The state of Ohio does not assume liability for the use or disclosure of any unredacted material.

(4) The board is required to comply with section 149.43 of the Revised Code, which is construed liberally in favor of broad access, and any doubt shall be resolved in favor of disclosure of public records.

(N) The board will make reasonable efforts to determine the initial approval or denial of a project submission within ninety days of the submission of a completed project petition in accordance with paragraph (E) of this rule.

The board shall be required to make the initial approval or denial of a project submission within one hundred and eighty days of the submission of a completed project petition in accordance with paragraph (E) of this rule. This timeframe may be extended by the board for good cause.

(O) Unless otherwise approved by the board, a petition shall be deemed abandoned if the petitioner fails to submit any requested documentation or information within thirty days after being notified by the board. The board shall not be required to act on any abandoned petition and the petition may be destroyed by board staff. If the petition is abandoned, the petitioner shall be required to resubmit a new petition for consideration pursuant to the requirements of this rule.