

**657—39.16(155A) Pharmacy pilot or demonstration research projects.** The purpose of this rule is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy. In reviewing projects, the board will consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage to a single applicant or group of applicants.

**39.16(1) Definitions.** For the purposes of this rule, the following definitions shall apply:

“Act” means Iowa Code chapter 155A, the Iowa pharmacy practice Act.

“Board” means the Iowa board of pharmacy.

“Practice of pharmacy” means the practice of pharmacy as defined in Iowa Code section 155A.3(37).

“Project” means a pilot or demonstration research project as described in this rule.

**39.16(2) Scope of project.** A project may not expand the definition of the practice of pharmacy. A project may include therapeutic substitution or substitution of medical devices used in patient care if such substitution is included under a collaborative pharmacy practice agreement pursuant to rule 657—39.13(155A).

**39.16(3) Board approval of a project.** Board approval of a project may include the grant of an exception to or a waiver of rules adopted under the Act or under any law relating to the authority of prescription verification and the ability of a pharmacist to provide enhanced patient care in the practice of pharmacy. Project approval, including exception to or waiver of board rules, shall initially be for a specified period of time not exceeding 18 months from commencement of the project. The board may approve the extension or renewal of a project following consideration of a petition that clearly identifies the project, that includes a report similar to the final project report described in paragraph 39.16(6)“a,” that describes and explains any proposed changes to the originally approved and implemented project, and that justifies the need for extending or renewing the term of the project.

**39.16(4) Applying for approval of a project.** A person 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:

a. *Responsible pharmacist.* Name, address, telephone number, and pharmacist license number of each pharmacist responsible for overseeing the project.

b. *Location of project.* Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy license number where the proposed project will be conducted.

c. *Project summary.* A detailed summary of the proposed project that includes at least the following information:

- (1) The goals, hypothesis, and objectives of the proposed project.
- (2) A full explanation of the project and how it will be conducted.
- (3) The time frame for the project including the proposed start date and length of study. The time frame may not exceed 18 months from the proposed start date of the project.
- (4) Background information or literature review to support the proposed project.
- (5) The rule or rules to be waived in order to complete the project and a request to waive the rule or rules.

(6) Procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver.

**39.16(5) Review and approval or denial of a proposed project.**

a. *Staff review.* Upon receipt of a petition for approval of a project, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration, board 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.

b. *Board review.* Upon review by the board of a petition for approval of a project, the board shall either approve or deny the petition. If the board approves the petition, the approval:

- (1) Shall be specific for the project requested;
- (2) Shall approve the project for a specific time period; and
- (3) May include conditions or qualifications applicable to the project.

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

*d. Documentation maintained.* Project documentation shall be maintained and available for inspection, review, and copying by the board or its representative for at least two years following completion or termination of the project.

**39.16(6)** *Presentation of reports.* 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.

*a. Final project report.* 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 three months after completion or termination of the project.

*b. Board review.* The board shall receive and review any report regarding the progress of a project and the final project report at a regularly scheduled meeting of the board. The report shall be an item on the open session agenda for the meeting.

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