Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

EMERGENCY RULE

20 CSR 2220-2.995 Board Approved Pilot and Research Projects

PURPOSE: This rule establishes application requirements and criteria for pilot projects authorized by section 338.143, RSMo.

*EMERGENCY STATEMENT: Section 338.143, RSMo, was enacted in 2019 which granted the board authority to approve and establish requirements for pharmacy pilot or demonstration research projects related to technology assisted verification or remote medication dispensing that are designed to enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services. Pursuant to section 338.143.4, RSMo, the board is required to submit a report to the General Assembly on related data or findings on or before December 31, 2022. The proposed emergency rule would establish requirements and criteria for potential pilot and demonstration projects to ensure patient safety and appropriate oversight. An early effective date is needed to allow potential participants to establish, apply for, operate, analyze, and report on research findings in sufficient time to allow the board to provide the legislatively mandated report by December 31, 2022. As a result, the Missouri State Board of Pharmacy finds the proposed rule is necessary to preserve a compelling governmental interest in that an early rule effective date is required to comply with the General Assembly's mandate to implement and report on project findings prior to December 31, 2022. Absent emergency action, the board and approved participants will be unable to meet the legislatively required deadlines prior to statutory expiration. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri** and **United States Constitutions**. The Missouri State Board of Pharmacy believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed September 13, 2019, becomes effective September 27, 2019, and expires March 24, 2020.*

(1) This rule establishes requirements for the approval and operation of pharmacy pilot or demonstration research projects related to technology assisted verification or remote medication dispensing that are designed to enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services, as authorized by section 338.143, RSMo.

(2) Applicants to operate a pilot program pursuant to this rule shall file an application on a form provided by the board. To be eligible, the applicant must hold a current and active license, registration, or permit from the board that is not under discipline.

(3) Proposal Requirements. Proposed pilot projects must be submitted to the board in writing and include-

(A) A one (1) page abstract of the project that includes the project's goals, purpose, scope, and proposed timelines;

(B) A narrative description of the following:

1. Activities that will be undertaken as part of the pilot project, including, the intended audience;

2. The goals and objectives of the project. Services and anticipated outcomes must be clearly described and align with section 338.143, RSMo;

3. A description of the capacity and structure the institution has in place to operate the proposed pilot program, including, staff and personnel who will be monitoring, supervising or participating in the pilot project and their relevant education, experience, or qualifications;

4. Procedures for training staff on project operations;

5. An explanation of how the proposal will enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services for Missouri citizens;

6. A projected timeline for implementation and completion of the proposed pilot project. The proposed pilot project must be eligible for completion within eighteen (18) months of approval, unless otherwise authorized by the board;

7. Evaluation measures for assessing impact and effectiveness; and

8. A plan for pilot project termination.

(4) Pilot Projects shall be awarded at the discretion of the board with due consideration to public protection, patient safety, feasibility, the needs of the state, and the impact on pharmacy practice. Approved pilot projects shall report on program activities, as requested by the board. Approval of a pilot project may be withdrawn or rescinded by the board for the following:

(A) Any grounds authorized for discipline under section 338.055.2, RSMo;

(B) Failure to report on project operations, as requested by the board;

(C) To prevent or avoid patient harm or undue patient risk;

(D) To protect the public health, safety, or welfare; or

(E) Exceeding/Failure to comply with approved project guidelines. Deviations from approved pilot project operations must be reported to the board within five (5) business days.

*AUTHORITY: sections 338.140 and 338.143, RSMo Supp. 2019. Emergency rule filed Sept. 13, 2019, effective Sept. 27, 2019, expires March 24, 2020. An emergency rule and a proposed rule covering this same material will be published in the October 15, 2019, issue of the **Missouri Register**.*

PUBLIC COST: This emergency rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the time the emergency is effective.

PRIVATE COST: This emergency rule will cost private entities three thousand thirty-two dollars ($3,032) in the time the emergency is effective.

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Commerce and Insurance
Division Title: State Board of Pharmacy
Chapter Title: General Rules

Rule Number and Title:	**20 CSR 2220-2.995 Board Approved Pilot and Research Projects**
Type of Rulemaking:	**Emergency Rule**

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
10	Entities applying to operate a pilot or research project pursuant to § 338.143	$ 3,032 *(in the time the emergency is effective)*

III. ASSUMPTIONS/WORKSHEETS

The following general estimations were used to calculate private fiscal costs:

1. Section 338.143, RSMo, authorizes the Board to approve pilot or demonstration research projects to enhance patient safety, increase patient outcomes, or expand access to pharmacy services. Based on communication with other states and potential project operators, the Board estimates approximately ten (10) entities may apply to operate a pilot or demonstration research project authorized by section 338.143.
2. Participation in a pilot/demonstration research project is voluntary and project parameters would be established by approved participants. However, the Board estimates it will take a pharmacist/researcher approximately five (5) hours to complete the descriptive narrative required to apply for Board approval.
3. An hourly pharmacist/researcher salary of $ 60.64 was estimated based on data reflected in the currently available United States Department of Labor, Bureau of Labor Statistics Occupational Outlook Handbook. As a result, the Board estimates a total cost of $ 3,032 over the life of the rule (10 applicants x $60.64 pharmacist hourly wage x 5 hours per descriptive narrative preparation).