

Department of Licensing and Regulatory Affairs
Bureau of Health Care Services

Pharmacy Pilot Project Procedures

The Michigan Public Health Code (Code), specifically MCL §333.17723 effective March 30, 2014, provides provisions to allow pharmacies to submit to the Department, a proposed pilot project. These pilot projects should be designed to utilize new or expanded technology or processes and to provide patients with better pharmacy products or provide pharmacy services in a more efficient manner. The focus should be on maintaining or improving patient care in the delivery of pharmacy services and improving patient outcomes. Pilot projects will be reviewed as an exception to a rule promulgated by the Board of Pharmacy. The Board will not grant an exception from any law relating to the practice of pharmacy. Projects that involve expanding the definition of the practice of pharmacy and/or provide for therapeutic substitution or substitution of medical devices used in patient care will not be considered.

Pilot Project Submission:

1. A pharmacy may submit a petition for the proposed pilot project, and currently there is no application or monitoring charges for a pilot project through September 30, 2014, the State's Fiscal Year-End. The Department will evaluate time and expenses related to pilot projects, and may impose fees in a future Fiscal Year. An applicant should submit a petition to the following address:

Department of Licensing & Regulatory Affairs
Bureau of Health Care Services
ATTN: MAPS/Pharmacy Section
P.O. Box 30454
Lansing, MI 48909

The petition must include the following:

- a. The name, address, telephone number, e-mail address, and the Michigan license number of the pharmacy and of the pharmacist responsible for overseeing the proposed pilot project;
- b. Specific location where the proposed pilot project will be conducted, a statement that the license of the pharmacy and pharmacist are current, is not under investigation for or subject to a sanction for any violation of the Code and will remain in good standing for the duration of the pilot program;
- c. Detailed summary of the proposed pilot project that includes the goals, hypothesis and objectives, if applicable, of the proposed pilot project;
- d. Full explanation of the proposed pilot project and how the pilot project will be conducted;
- e. The initial time frame for the pilot project, including proposed start date and length of project, which must not exceed 18 months from the date of initial approval;
- f. All background information and literature review, if applicable, to support the proposed pilot project;
- g. Identification of the rules promulgated from which the requestor is requesting an exception in order to complete the proposed pilot project and a request for that exception, if applicable;
- h. Procedures used to ensure that the public's health and safety are not compromised as a result of the exception to the rule being granted, if applicable; and,

- i. Procedures used to protect the identity and privacy of patients in accordance with existing federal and state law, including HIPAA.
2. Once submitted, the department will send a letter of acknowledgement, advising that the department will review the proposed pilot program and complete the '*Review of Proposed Pilot Project*' form within 90 days of receipt by the department.

Department Denial

- a. The department will contact petitioner stating reason(s) for the denial.

Department Approval

- a. Review pharmacy license and pharmacist license for investigation and/or sanction history;
- b. Forward completed and approved '*Review of Proposed Pilot Project*' form to the Board of Pharmacy for inclusion at the next regularly scheduled meeting;
- c. Notify Petitioner of the Board's project review at least two weeks prior to the scheduled Board of Pharmacy meeting in the event the petitioner would like to provide a presentation to the Board.
- d. A department representative will attend the Board of Pharmacy meeting when the pilot project is to be considered.
- e. The Board of Pharmacy will review the '*Review of Proposed Pilot Project*' form to decide whether to approve or deny the proposed pilot project.

Board of Pharmacy: Project Approval

- a. Board representative will sign the '*Review of Proposed Pilot Project*' indicating the board's approval.
- b. A department representative will notify the petitioner of the Board's approval
- c. The department will obtain and review required progress reports at intervals specified in the approval.
- d. Upon completion of the pilot project, the department will obtain a summary report from the petitioner detailing the results of the project and conclusions drawn from the results of the project.
- e. Once the pilot project has ended, the department will complete the '*Evaluation of Completed Pilot Project*' form and submit it to the Board of Pharmacy for inclusion at the next regularly scheduled meeting for their review.
- f. The Board of Pharmacy will review the summary and conclusions of the pilot project. If approved, an extension will be granted to allow the project to continue on a permanent basis while rules are promulgated

Possible Pilot Project Requirements:

Notification of approval for the pilot project may include the following requirements:

- A specified time period for the operation of the pilot project (not to exceed 18 months). An extension period of up to an additional 18 months may be granted if Board of Pharmacy rules need to be promulgated in order to allow the pilot project to be conducted on a permanent basis.
- Any additional conditions or qualifications required for the pilot project.
- A requirement to notify patients that pharmacy services are being provided as part of a pilot project, and in a manner required by the department.

- Random inspection(s) by the department to review pilot project documentation and project site at any time during the review process and after the pilot project is approved.
- Submission of progress reports at specified intervals, a summary of the results of the project, and conclusions drawn from the result of the project within three (3) months after completion of the pilot project.

Board of Pharmacy: Project Denial

- a. Board representative will sign the '*Review of Proposed Pilot Project*' indicating the board's denial.
 - b. A department representative will contact the petitioner with the results of the review and the reason(s) for the denial.
3. **NOTE:** The department or board may suspend the operation of the pilot project if it determined that the petitioner or any person involved with the pilot project has deviated from the plan of operation that was approved.

Attachment: Sample Petition format

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
Bureau of Health Care Services

**Pharmacy Pilot Program
Sample Petition**

(Please refer to the instructions for further direction.)

I.) Initial Information:

[Please refer to Procedure 1(a)]

[Please refer to Procedure 1(b)]

II.) Pilot Summary/Description:

[Please refer to Procedure 1(c)]

[Please refer to Procedure 1(d)]

[Please refer to Procedure 1(e)]

III.) Background Information/Literature Review:

[Please refer to Procedure 1(f)]

IV.) Pharmacy Rule Deviation & Reason(s) Why:

[Please refer to Procedure 1(g)]

V.) Public Safety/Health/Security:

[Please refer to Procedure 1(h)]

[Please refer to Procedure 1(i)]

Name: _____

Signature: _____

Date: _____