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BILL ANALYSIS

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Senate Bill 373 (as introduced 5-21-13)
Sponsor: Senator Goeff Hansen
Committee: Health Policy

Date Completed: 5-23-13

CONTENT

The bill would amend the Public Health Code to do the following:

- **Require the Michigan Board of Pharmacy to establish a process for the approval of up to 25 pilot projects designed to provide better pharmacy products or more efficient pharmacy services.**
- **Authorize the Board to grant an exception to a Board rule to facilitate the conduct of an approved pilot program.**
- **Require a person to petition the Department of Licensing and Regulatory Affairs (LARA) for approval of a proposed pilot project.**
- **Require LARA to conduct an initial review of a petition for completeness and appropriateness, and create a review committee to make recommendations regarding the Board's approval or denial of a project.**
- **Require the pharmacist responsible for overseeing an approved project to submit periodic progress reports, as well as a summary of the results after the project's completion.**
- **Require the review committee to review the summary and provide a report on the results to the Board.**

Specifically, beginning 90 days after the bill took effect, the Board of Pharmacy, in consultation with the LARA, would have to establish and administer a process by which the Board could approve up to 25 pilot projects. The Board could not approve more than one pilot project to a person who petitioned for a project.

The Board could only approve a pilot project that was designed to use new or expanded technology or processes and to provide patients with better pharmacy products or more efficient pharmacy services. The Board could not approve a pilot project that did any of the following:

- Expanded the definition of the practice of pharmacy.
- Provided for the therapeutic substitution or substitution of medical devices used in patient care.
- Gave the person petitioning for the project a competitive edge over any other person engaged in the practice of pharmacy.

The Board could grant a person conducting an approved pilot project an exception to a rule promulgated by the Board, but could not grant an exception to any law relating to the

practice of pharmacy. An exception to a rule would have to be for a specified period of time, which could not exceed 18 months unless extended as described below.

A person who wished the Board to consider a pilot project for approval would have to submit to LARA a petition containing all of the following information:

-- The name, address, telephone number, electronic mail address, and license number of the pharmacist responsible for overseeing the proposed project.
-- The specific location and, if applicable, the license number of the pharmacy where the proposed project would be conducted.

In addition, the petition would have to contain a detailed summary of the proposed project that included all of the following:

-- The proposed project's goals, hypothesis, and objectives, as applicable.
-- A full explanation of the project and how it would be conducted.
-- The initial time frame for the project, including the proposed start date and length of the project.
-- All background information and literature review, as applicable, to support the proposed project.
-- If applicable, identification of the Board rules from which the petitioner was requesting an exception in order to complete the project, and a request for the exception.
-- If applicable, procedures the petitioner would use during the project to ensure that the public's health and safety were not compromised as a result of the Board's granting an exception.

Within 30 business days after receiving a petition, LARA would have to review it for completeness and appropriateness. If the petition were incomplete or inappropriate for consideration for any reason, including violation of law, LARA would have to return it with a letter of explanation.

Upon determining that a petition was complete and appropriate, LARA would have to create a review committee that consisted of appropriate Department staff, at least one Board member, and other resource personnel considered necessary by the Department or the Board. The committee would have to review the petition and submit a written recommendation to the Board regarding approval or denial of the proposed project. The committee would have to submit a copy of its recommendation to the petitioner at least two weeks before the Board meeting at which the Board would consider the recommendation.

The Board would have to allow the petitioner and a representative of the committee equal time for presentations if requested by the committee or the Board. Upon hearing the presentations, if applicable, the Board would have to approve or deny the petition. If the Board approved it, the approval would have to be specific for that pilot project and for a specified period of time, which could not exceed 18 months. If the Board considered it appropriate, approval of a project could include conditions or qualifications.

The petitioner would have to allow LARA or the Board to inspect and review project documentation and the project site at any time during the review process and after the project was approved. The pharmacist responsible for overseeing an approved project would have to submit progress reports at intervals specified by the Board, in addition to a summary of the project's results and conclusions drawn from them within three months after the project was completed.

The review committee for the project or a similar review committee created by the Board would have to review the summary of results and submit to the Board a written report regarding those results. The committee would have to submit a copy of the report to the

petitioner at least two weeks before the meeting at which the Board would consider the report. The Board would have to give the petitioner and a representative of the committee equal time for presentations, if requested by the committee or the Board.

If determined appropriate, the Board could extend the time period for conducting a pilot project for an additional period of 18 months. The Board could not grant an extension that would result in a total time period for the project that would exceed 36 months. If the Board determined that a project for which an exception to a rule had been granted should be extended so that rules could be promulgated in order to allow the project to be conducted on a permanent basis, the Board could extend the exception for an additional 18 months. The Board and LARA could use the review committee process prescribed in the bill for the purpose of authorizing extensions.

Proposed MCL 333.17723 Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bill would have a minor, but likely negative impact on the Bureau of Health Care Services in the Department of Licensing and Regulatory Affairs, and no fiscal impact on local units of government. Under the bill, the Michigan Board of Pharmacy would have to review and approve potential pilot projects. The Department would have to initially review and create a review committee for petitions; this could introduce some new costs, which would be borne by existing resources.

Fiscal Analyst: Josh Sefton