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BILL ANALYSIS

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Senate Bill 373 (Substitute S-2 as passed by the Senate)
Sponsor: Senator Goeff Hansen
Committee: Health Policy

Date Completed: 9-26-13

RATIONALE

In recent years, there has been a movement in the health care industry, including the pharmacy business, to improve the delivery of care through technology modernization and other efficiencies. In their efforts to adapt to a changing economy, some pharmacists have identified new ways of doing business that might lower costs, mitigate geographical challenges, and otherwise result in better customer service. In some cases, however, these ideas conflict with administrative rules and thus cannot be implemented and tested. It has been suggested that a program should be created to allow pharmacists to petition the Department of Licensing and Regulatory Affairs for approval of pilot projects and for rule exceptions that would enable them to carry out approved projects.

CONTENT

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

- **Permit the Department of Licensing and Regulatory Affairs (LARA) to establish a process for the approval of up to 25 pilot projects designed to provide better pharmacy products or more efficient pharmacy services.**
- **Require LARA, in consultation with the Michigan Board of Pharmacy, to establish and administer a process to receive, review, and accept or deny petitions for proposed pilot projects.**
- **Require LARA to designate individuals who would review petitions.**
- **Authorize LARA, in consultation with the Board, to grant an exception to a Board rule to facilitate the conduct of an approved pilot program.**
- **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 individuals designated to review petitions to review the progress report and the summary, and report on the results to LARA, which would have to give a copy to the Board.**

The bill would take effect 90 days after it was enacted.

Specifically, LARA could approve up to 25 pilot projects designed to use new or expanded technology or processes and to provide patients with better pharmacy products or more efficient pharmacy services. In consultation with the Michigan Board of Pharmacy, LARA would have to do all of the following:

- Establish and administer a process to receive, review, and accept or deny petitions for proposed pilot projects.
- Establish time frames for the receipt, review, and approval or denial of petitions.
- Designate the individuals who would review petitions.

The Department could charge petitioners a filing fee sufficient to cover its costs incurred while administering and monitoring the pilot projects.

If it determined necessary, LARA could further limit the number of approved pilot projects based on the scope and type of petitions received. The Department could not approve a pilot project that expanded the definition of the practice of pharmacy or provided for the therapeutic substitution or substitution of medical devices used in patient care.

In consultation with the Board, LARA could grant a petitioner 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 petitioner who wished LARA to consider a pilot project for approval would have to submit a petition containing the name, address, telephone number, electronic mail address, and Michigan license number of the pharmacist responsible for overseeing the proposed project. The petition also would have to include the specific location where the proposed project would be conducted, as well as the Michigan license number of the pharmacy and a statement that the license of the pharmacy and any pharmacist involved with the project was current and would remain in good standing for the project's duration.

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 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 granting of an exception.
-- The procedures the petitioner would use to protect the identity and privacy of patients in accordance with existing Federal and State law and consistent with regulations promulgated under the Health Insurance Portability and Accountability Act.

Upon approving a petition, LARA would have to specify a time period for the operation of the project, which could not exceed 18 months unless extended as described below. In consultation with the Board, LARA could include appropriate conditions or qualifications on its approval.

The petitioner would have to allow LARA 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 the following to LARA:

-- Progress reports at intervals specified by the Department.
-- A summary of the project's results and conclusions drawn from them within three months after the project was completed.

The individuals designated to review petitions would have to review the progress reports and the summary of results and, within 90 days after receiving the summary, submit to LARA a written report regarding those results. The Department would have to give a copy of the report to the Board. The designated individuals 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 allow the petitioner to make a presentation, if requested by the Board.

If determined appropriate at the Board meeting and if approved by LARA, the Board could extend the time period for conducting a pilot project for an additional period of up to 18 months. The Department, in consultation with the Board, could not grant an extension that would result in a total time period for the project that would exceed 36 months. If LARA, in consultation with 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, LARA could extend the exception for an additional 18 months.

Proposed MCL 333.17723

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Economic challenges and an increasingly technologized world have had a significant impact on the pharmacy industry. For example, many pharmacies in rural areas have closed because their sales numbers could not support the salary of a licensed pharmacist. Reportedly, more than 900 rural pharmacies nationwide have closed in the last six years, leading to nearly 6,000 lost jobs and 4.8 million underserved residents.

The adoption of new technologies and other business practices can return struggling pharmacies to profitability, create jobs, and help ensure that all populations have access to pharmacy services. In some cases, though, existing administrative rules limit a pharmacy's options to function more efficiently. For instance, it has been proposed that a pharmacist could effectively supervise several pharmacies via the internet, thereby enabling the operation of facilities in rural locations where operational costs currently render pharmacy service impractical. Under a current rule, however, a pharmacist may oversee only one pharmacy at a time.

The pilot programs under the bill would provide opportunities for pharmacists to try out innovative ideas and emerging technologies on a small scale under controlled conditions, with oversight from LARA to ensure that protections for consumer health and safety were maintained. The experience gained from the approved projects could be useful in identifying any regulatory or statutory changes that might improve access to and quality of pharmacy services.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bill would have a likely neutral fiscal impact on the Department of Licensing and Regulatory Affairs and no fiscal impact on local units of government. The bill would introduce some new costs to LARA associated with reviewing, administering, and monitoring pilot projects. However the bill also would allow LARA to charge petitioners for pilot projects a filing fee sufficient to cover the costs LARA would incur while administering and monitoring the pilot projects. This filing fee would presumably cover new costs introduced to LARA under the bill.

Fiscal Analyst: Josh Sefton