Legislative Analysis

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PHARMACY PILOT PROJECTS

Senate Bill 373 (Proposed H-1)
Sponsor: Sen. Goeff Hansen
House Committee: Health Policy
Senate Committee: Health Policy

Complete to 11-4-13

A SUMMARY OF SENATE BILL 373 (PROPOSED SUBSTITUTE H-1)

BRIEF SUMMARY:

The bill would do the following:

- Allow the Board of Pharmacy to approve up to 10 pilot projects designed to utilize new or expanded technologies or processes to provide patients with better pharmacy products or more efficient pharmacy services.
- Require LARA, among other things, to establish and administer the process to receive, review, and accept or deny petitions for the proposed pilot projects.
- Require LARA to designate individuals to review the petitions.
- Require the Board to reject petitions under certain conditions; for instance, any that expanded the definition of the practice of pharmacy.
- Allow LARA, in consultation with the Board, to grant an exception to an administrative rule for a limited time for an approved pilot project.
- Specify the information that a pharmacist would need to include on a petition to LARA for a proposed pilot project.
- Require LARA to set the time period for the operation of an approved project but limit any project duration to no more than 36 months.
- Require the pharmacist overseeing a pilot project to submit certain reports and summaries to LARA.
- Require the individuals designated to review the petitions to also review the reports and summaries and report on the results to LARA, which would have to give a copy to the Board.
- Allow LARA to charge a filing fee to cover the permitting process.

The bill would take effect 90 days after enactment.

DETAILED SUMMARY:

Senate Bill 373 would add a new section to the Public Health Code to allow the Board of Pharmacy to approve pilot projects 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 (MCL 333.17723, proposed). The Board would have to ensure that an approved pilot project be focused on maintaining or improving patient care in the delivery of pharmacy services and improving patient outcomes.

Board of Pharmacy. The Board could not approve more than 10 pilot projects under the bill. If necessary, the Board or the Department of Licensing and Regulatory Reform (LARA) could further limit the number of approved pilot projects based on the scope and type of petitions received. 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.
- Allowed a pharmacy or pharmacist to be involved with a pilot project if the pharmacy or pharmacist's license is not current or is under investigation for or subject to a sanction for a violation of the Public Health Code.

LARA. The department would have to do all of the following:

- Establish and administer a process (and the time frames) to receive, review, and accept or deny petitions for proposed pilot projects.
- Designate the individuals who will review and evaluate the petitions.
- Upon approval of a petition, specify a time period for the operation of that pilot project. The period could not exceed 18 months, but could be extended for no more than an additional 18 months as specified in the bill.

LARA could charge petitioners a filing fee sufficient to cover its costs incurred while administering and monitoring the pilot projects. In consultation with the Board, LARA could include appropriate conditions or qualifications on the approval of a pilot project.

Either LARA or the Board could suspend the operation of a pilot project if it determined that the petitioner or any person involved with the pilot project had deviated from the approved plan of operation.

The Petitioner. A petitioner who wishes the Board to consider a pilot project for approval would have to submit a petition to LARA that included the following information:

- 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 (not to exceed 18 months), 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.

- The name, address, email, telephone number, and Michigan license number of the pharmacist overseeing the pilot project.
- The specific location where the pilot project will be conducted.

The petitioner must allow LARA to inspect and review pilot project documentation and the project site at any time during the review process and after project approval. The pharmacist responsible for overseeing an approved pilot project must forward to LARA progress reports at intervals specified by the department and a summary of the project's results and conclusions drawn from those results within three months of the project's completion.

The petitioner could be required by LARA or the Board to notify patients in the manner required by LARA or the Board that pharmacy services are being provided as part of a pilot project.

Exceptions to administrative rules. LARA, in consultation with the Board, could grant to a petitioner conducting an approved pilot project an exception to a departmental rule–but not to any law relating to the practice of pharmacy–for a specified period not to exceed 18 months. The exception could be extended an additional 18 months to allow for rules to be promulgated in order to allow the pilot project to be conducted on a permanent basis.

Review of progress reports and summaries. The individuals designated by LARA to review and evaluate the petitions for the pilot projects would also have to review the progress reports and the summaries of the results of completed projects. A written report would have to be submitted to LARA by these individuals regarding the results of a pilot project within 90 days of receipt of the summary of the results submitted by the pharmacist who had provided oversight.

LARA would have to provide a copy of the written report to the Board. The individuals who had reviewed the progress reports would have to submit a copy of the written report to the petitioner at least two weeks before the Board meeting at which the report will be considered by the Board. Upon request by the petitioner, the Board would have to allow the petitioner to make a presentation.

FISCAL IMPACT:

Senate Bill 373 would have a neutral fiscal impact on the Department of Licensing and Regulatory Affairs (LARA) because SB 373 would authorize LARA to establish filing fees that LARA determines are sufficient to offset the costs of administering, monitoring, and reviewing pharmacy product and service pilot projects under SB 373.

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■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.