

Act No. 267
Public Acts of 2013
Approved by the Governor
December 21, 2013
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December 30, 2013
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**STATE OF MICHIGAN
97TH LEGISLATURE
REGULAR SESSION OF 2013**

Introduced by Senator Hansen

ENROLLED SENATE BILL No. 373

AN ACT to amend 1978 PA 368, entitled "An act to protect and promote the public health; to codify, revise, consolidate, classify, and add to the laws relating to public health; to provide for the prevention and control of diseases and disabilities; to provide for the classification, administration, regulation, financing, and maintenance of personal, environmental, and other health services and activities; to create or continue, and prescribe the powers and duties of, departments, boards, commissions, councils, committees, task forces, and other agencies; to prescribe the powers and duties of governmental entities and officials; to regulate occupations, facilities, and agencies affecting the public health; to regulate health maintenance organizations and certain third party administrators and insurers; to provide for the imposition of a regulatory fee; to provide for the levy of taxes against certain health facilities or agencies; to promote the efficient and economical delivery of health care services, to provide for the appropriate utilization of health care facilities and services, and to provide for the closure of hospitals or consolidation of hospitals or services; to provide for the collection and use of data and information; to provide for the transfer of property; to provide certain immunity from liability; to regulate and prohibit the sale and offering for sale of drug paraphernalia under certain circumstances; to provide for the implementation of federal law; to provide for penalties and remedies; to provide for sanctions for violations of this act and local ordinances; to provide for an appropriation and supplements; to repeal certain acts and parts of acts; to repeal certain parts of this act; and to repeal certain parts of this act on specific dates," (MCL 333.1101 to 333.25211) by adding section 17723.

The People of the State of Michigan enact:

Sec. 17723. (1) Subject to this section, the board may approve a pilot project that is 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 board shall ensure that a pilot project it approves under this section is focused on maintaining or improving patient care in the delivery of pharmacy services and improving patient outcomes. The department may charge petitioners a filing fee sufficient to cover the department's costs incurred while administering and monitoring the pilot project under this section.

(2) The department shall do all of the following:

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

(3) The board shall not approve more than 10 pilot projects under this section. If it determines necessary, the board or department may further limit the number of approved pilot projects based on the scope and type of petitions for proposed pilot projects received.

(4) The board shall not approve a pilot project that does any of the following:

- (a) Expands the definition of the practice of pharmacy.

(b) Provides for the therapeutic substitution or substitution of medical devices used in patient care.

(c) Allows a pharmacy or pharmacist to be involved with a pilot project if the pharmacy's or pharmacist's license is not current or is under investigation for or subject to a sanction for a violation of this act.

(5) The department, in consultation with the board, may grant to a petitioner conducting an approved pilot project under this section an exception to a rule promulgated under this part. The department shall not grant an exception under this subsection from any law relating to the practice of pharmacy. The department shall grant an exception under this subsection for a specified period of time, which period must not exceed 18 months unless extended under subsection (12).

(6) A petitioner who wishes the board to consider a pilot project for approval under this section shall submit to the department a petition that contains all of the following information:

(a) The name, address, telephone number, electronic mail address, and Michigan license number of the pharmacist responsible for overseeing the proposed pilot project.

(b) The specific location where the proposed pilot project will be conducted. The petitioner shall include the Michigan license number of the pharmacy and a statement that the Michigan license of the pharmacy and any pharmacist involved with the pilot project is current, is not under investigation for or subject to a sanction for a violation of this act, and will remain in good standing for the duration of the pilot project.

(c) A detailed summary of the proposed pilot project that includes all of the following:

(i) The goals, hypothesis, and objectives, as applicable, of the proposed pilot project.

(ii) A full explanation of the proposed pilot project and how the project will be conducted.

(iii) The initial time frame for the pilot project, including the proposed start date and length of the project, which initial time frame must not exceed 18 months.

(iv) All background information and literature review, as applicable, to support the proposed pilot project.

(v) If applicable, identification of the rules promulgated under this part from which the petitioner is requesting an exception as provided in subsection (5) in order to complete the proposed pilot project and a request for that exception.

(vi) If applicable, procedures the petitioner will use during the proposed pilot project to ensure that the public's health and safety are not compromised as a result of an exception to a rule being granted under subsection (5).

(vii) The procedures the petitioner will 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 of 1996, Public Law 104-191.

(7) Upon approval of a petition for a pilot project, the department shall specify a time period for the operation of that pilot project, which period must not exceed 18 months unless extended under subsection (11). The department, in consultation with the board, may include appropriate conditions or qualifications on the approval of a pilot project. The department or board may suspend the operation of a pilot project if it determines that the petitioner or any person involved with the pilot project has deviated the operation of the pilot project from the plan of operation that was approved.

(8) If determined appropriate for the pilot project approved under this section, the board or department may require the petitioner to notify patients that pharmacy services are being provided as part of a pilot project. If required under this subsection, the petitioner shall notify patients in the manner required by the board or department.

(9) The petitioner shall allow the department to inspect and review pilot project documentation and the pilot project site at any time during the review process and after the pilot project is approved. The pharmacist responsible for overseeing an approved pilot project shall forward all of the following to the department:

(a) Progress reports at intervals specified by the department.

(b) A summary of the results of the project and conclusions drawn from the results of the project within 3 months after completion of the pilot project.

(10) The individuals designated to review and evaluate petitions under subsection (2)(c) shall review the progress reports and the summary of the results of the pilot project submitted under subsection (9). Within 90 days after receipt of the summary of the results of the pilot project under subsection (9), the individuals designated to review and evaluate petitions under subsection (2)(c) shall submit a written report to the department regarding the results of the pilot project. The department shall provide a copy of the written report submitted under this subsection to the board. The individuals designated to review and evaluate petitions under subsection (2)(c) shall submit a copy of the written report to the petitioner at least 2 weeks before the board meeting at which the report will be considered by the board. Upon the request of the petitioner, the board shall allow the petitioner to make a presentation to the board.

(11) If determined appropriate by the board at the meeting at which the written report is considered under subsection (10), and if approved by the department, the specified period of time for conducting a pilot project under subsection (7) may be extended for an additional period of up to 18 months. The board or department shall not grant an extension that would result in a specified period of time for conducting a pilot project under this section to exceed 36 months.

(12) If the department, in consultation with the board, determines that a pilot project for which an exception to a rule has been granted under subsection (5) should be extended so that rules may be promulgated in order to allow the pilot project to be conducted on a permanent basis, the department may extend the exception to the rule for an additional period of up to 18 months.

Enacting section 1. This amendatory act takes effect 90 days after the date it is enacted into law.

This act is ordered to take immediate effect.

Carol Morey Viventi

Secretary of the Senate

Jay E. Randall

Clerk of the House of Representatives

Approved

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Governor