Act No. 133
Public Acts of 2015
Approved by the Governor
September 30, 2015
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STATE OF MICHIGAN
98TH LEGISLATURE
REGULAR SESSION OF 2015

Introduced by Senator Green

ENROLLED SENATE BILL No. 468

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," by amending sections 17739a, 17739b, 17739c, and 17748a (MCL 333.17739a, 333.17739b, 333.17739c, and 333.17748a), sections 17739a, 17739b, 17739c as added by 2014 PA 285 and section 17748a as added by 2014 PA 280.

The People of the State of Michigan enact:

Sec. 17739a. (1) Subject to subsection (2), the department may license an individual who meets all of the following requirements as a pharmacy technician under this part:

(a) Submits a completed application to the department on a form prescribed by the department.

(b) Except as otherwise provided in subsection (4), graduated from an accredited high school or comparable school or educational institution or passed the general educational development test or other graduate equivalency examination.

(c) Satisfies the requirements of section 16174.

(d) Except as otherwise provided in subsection (4), passes and submits proof to the department of passage of any of the following:

(*i*) The certified pharmacy technician examination given by the Pharmacy Technician Certification Board.

(*ii*) The certified pharmacy technician examination given by the National Healthcareer Association.

(*iii*) Any other nationally recognized and administered certification examination approved by the board.

(*iv*) An employer-based training program examination that is approved by the board and covers job descriptions, pharmacy security, commonly used medical abbreviations, routes of administration, product selection, final check by pharmacists, guidelines for the use of pharmacy technicians, pharmacy terminology, basic drug information, basic calculations, quality control procedures, state and federal laws and regulations regarding pharmacy technician duties, pharmacist duties, pharmacy intern duties, prescription or drug order processing procedures, drug record-keeping requirements, patient confidentiality, and pharmacy security and drug storage.

(2) An individual who is not a pharmacist, pharmacist intern, or pharmacy technician shall not perform any of the functions described in section 17739(1) for a pharmacy.

(3) A pharmacist shall not allow any individual employed or otherwise under the personal charge of the pharmacist to violate subsection (2). A person that owns, manages, operates, or conducts a pharmacy shall not allow any individual employed or otherwise under the control of that person to violate subsection (2).

(4) An individual who meets any of the following is not required to meet the requirements of subsection (1)(b) and (d) to be eligible for a license under subsection (1):

(a) As provided in section 16171(a), is a student in a pharmacy technician program approved by the board.

(b) Is applying for a temporary license under section 17739b.

(c) Is applying for a limited license under section 17739c.

Sec. 17739b. (1) Subject to section 17739a(4), the department may issue a temporary license as a pharmacy technician to an individual who is preparing for the examination under section 17739a(1)(d). Notwithstanding section 16181, the term of a temporary license issued under this section expires 1 year after the date the temporary license is issued.

(2) An individual requesting a temporary license under this section shall submit a completed application, on a form prescribed by the department, to the department and pay the applicable fee under section 16333.

(3) An individual who holds a temporary license as a pharmacy technician issued under subsection (1) is subject to all of the requirements of this part, and rules promulgated by the department in consultation with the board, applicable to pharmacy technicians except the examination requirement under section 17739a(1)(d).

Sec. 17739c. (1) In addition to the requirement of section 16182 and subject to section 17739a(4), the department may issue a limited license as a pharmacy technician to an individual if all of the following are met:

(a) The individual was employed as a pharmacy technician by a pharmacy on December 22, 2014 and has been continuously employed by that pharmacy since that date.

(b) The individual submits a completed application to the department on a form prescribed by the department and meets the requirements of section 16174.

(c) The individual provides documentation of satisfactory employment as a pharmacy technician for a minimum of 1,000 hours during the 2-year period immediately preceding the date of his or her application under subdivision (b).

(d) The applicable fee under section 16333 is paid.

(2) Except as otherwise provided in subsection (5), an individual who holds a limited license under this section may only act as a pharmacy technician for the pharmacy described in subsection (1)(a) and only until 1 of the following occurs:

(a) He or she is no longer employed by that pharmacy to perform those functions.

(b) He or she performs any of those functions for another pharmacy.

(3) The term of a limited pharmacy technician license issued by the department under this section is the same as a pharmacy technician license issued by the department under section 17739a.

(4) An individual who holds a limited pharmacy technician license issued under this section is subject to all of the requirements of this part, and the rules promulgated by the department in consultation with the board, except the examination requirement under section 17739a(1)(d).

(5) An individual who is employed as a pharmacy technician by an employer that operates multiple licensed pharmacy locations may work as a limited license pharmacy technician at any of the employer's licensed pharmacy locations in this state.

Sec. 17748a. (1) Beginning September 30, 2014, an applicant for a new pharmacy license for a pharmacy that will provide compounding services for sterile pharmaceuticals shall submit verification of current accreditation through a national accrediting organization approved by the board or verify the pharmacy is in the accreditation process. The department shall not issue a license to a pharmacy described in this subsection that is not accredited unless the applicant demonstrates compliance with USP standards in a manner determined by the board.

(2) By September 30, 2016, a pharmacy that is licensed on September 30, 2014 and that provides compounding services for sterile pharmaceuticals must be accredited by a national accrediting organization approved by the board, be verified by the board as being in the accreditation process, or be in compliance with USP standards in a manner determined by the board.

(3) Notwithstanding any provision of part 161 to the contrary, a pharmacy that provides compounding services for sterile pharmaceuticals shall submit with a license renewal application verification of current accreditation or compliance with USP standards, as applicable.

(4) A person that provides services consistent with an outsourcing facility shall comply with requirements of the FDA applicable to compounding services for sterile pharmaceuticals.

(5) A pharmacy shall notify the department of a complaint filed by another state in which the pharmacy is licensed for violations of that state's pharmacy laws, an investigation by federal authorities regarding violations of federal law, or an investigation by any agency into violations of accreditation standards regarding compounding activities within 30 days of knowledge of the complaint or investigation.

(6) Except for distribution within a hospital or another health care entity under common control when regulated by federal law, a pharmacist shall maintain a record of a compounded sterile pharmaceutical in the same manner and for the same retention period as prescribed in rules for other prescription records. The pharmacist shall include, but is not limited to including, all of the following information in the record required under this subsection:

(a) The name, strength, quantity, and dosage form of the compounded pharmaceutical.

(b) The formula to compound that includes mixing instructions, all ingredients and their quantities, and any additional information needed to prepare the compounded pharmaceutical.

(c) The prescription number or assigned internal identification number.

(d) The date of preparation.

(e) The manufacturer and lot number of each ingredient.

(f) The expiration or beyond-use date.

(g) The name of the person who prepared the compounded pharmaceutical.

(h) The name of the pharmacist who approved the compounded pharmaceutical.

(7) A pharmacist shall not offer excess compounded pharmaceuticals to other pharmacies for resale. A compounding pharmacy shall not distribute samples or complimentary starter doses of a compounded pharmaceutical to a health professional.

(8) A compounding pharmacy may advertise or otherwise promote the fact that they provide compounding services.

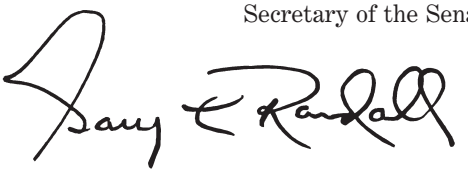
(9) Based on the existence of a health professional/patient relationship and the presentation of a valid prescription, or in anticipation of the receipt of a prescription based on routine, regularly observed prescription patterns, a pharmacist may compound for a patient a nonsterile or sterile pharmaceutical that is not commercially available in the marketplace.

(10) Notwithstanding any provision of this act to the contrary, a person shall not compound and manufacture drug products or allow the compounding and manufacturing of drug products at the same location.

(11) The department, in consultation with the board, may promulgate rules regarding conditions and facilities for the compounding of nonsterile and sterile pharmaceuticals.

This act is ordered to take immediate effect.

Secretary of the Senate



Clerk of the House of Representatives

Approved ----------

Governor