



STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES

RICK SNYDER
GOVERNOR

MIKE ZIMMER
ACTING DIRECTOR

Memorandum

DATE: September 2014

TO: All Pharmacies and Pharmacists

FROM: Bureau of Health Care Services

SUBJECT: New Legislation: Compounding Pharmacy and Other Requirements

Public Act 280 of 2014 (Senate Bill 704 of 2013) was recently signed into law by Governor Snyder. The Public Act sets forth new requirements for pharmacists or pharmacies that compound sterile and non-sterile pharmaceuticals and establishes a requirement for a "Pharmacist-in-charge." The legislation stemmed from tainted compounded drugs and a nationwide outbreak of meningitis that resulted in deaths.

Senate Bill 704 amends Part 161 (General Provisions) and Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code, 1978 PA 368. Below are summary highlights from Legislative analyses:

- Require a person providing compounding services in this State to be licensed as a pharmacy or manufacturer, and require an outsourcing facility to be licensed as a pharmacy.
- Require an applicant for a pharmacy license for a pharmacy that would provide compounding services for sterile pharmaceuticals, to submit verification of current accreditation through a national accrediting organization.
- Create an application process and standards for a pharmacist or pharmacy compounding pharmaceuticals for a prescriber, health facility, or agency without a prescription.
- Prohibit a pharmacist from compounding commercially available pharmaceuticals unless the commercially available pharmaceutical was modified to produce a significant difference and was not available in normal distribution channels to meet the patient's needs in a timely manner.

-- Require a pharmacy to notify the Department of Licensing and Regulatory Affairs (LARA) of a complaint regarding compounding activities filed by another state for violation of that state's pharmacy laws, an investigation by Federal authorities regarding a violation of Federal law, or

an investigation by any agency into a violation of accreditation standards, within 30 days of knowledge of the investigation or complaint.

-- Require an out-of-State applicant or licensee to reimburse LARA for expenses incurred in an inspection or investigation of the applicant or licensee.

-- Require LARA to maintain, post, and update on a quarterly basis, a list of pharmacies and pharmacists authorized to compound pharmaceuticals for a prescriber, health facility, or agency.

-- Allow LARA to promulgate rules regarding conditions and facilities for compounding pharmaceuticals.

-- Require a pharmacist to maintain records of compound sterile pharmaceuticals.

-- Require a pharmacy, manufacturer, or wholesale distributor to designate a licensed pharmacist as the pharmacist in charge (PIC), and establish the duties of a PIC.

-- Require certain applicants for new pharmacies, manufacturers, or wholesale distributors to undergo a criminal history check.

-- Prescribe criminal penalties for violations of statutory provisions and requirements.

-- Provide for the summary suspension of a pharmacy license if the Department of Licensing and Regulatory Affairs receives a notice of imminent risk to public health or safety from the United States Food and Drug Administration (FDA) or the Centers for Disease Control and Prevention (CDC).

This is only a summary and does not encompass all requirements of the legislation. We encourage you to review a complete copy of the Public Act and Legislative Bill Analyses at the Michigan Legislature's website. Direct webpage address:

<http://legislature.mi.gov/doc.aspx?2013-SB-0704>