Legislative Analysis



HOSPITAL PHARMACIES; AUTOMATED DISPENSING DEVICES Phone: (517) 373-8080 http://www.house.mi.gov/hfa

House Bill 5877 as enacted Public Act 528 of 2016

Sponsor: Rep. Daniela Garcia House Committee: Health Policy Senate Committee: Health Policy

Complete to 1-18-17

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BRIEF SUMMARY: House Bill 5877 amends the Public Health Code to allow a pharmacy that is owned and operated by a hospital licensed under Article 17 of the Code to operate an automated dispensing device in another location affiliated with the hospital. The bill takes effect April 9, 2017.

FISCAL IMPACT: House Bill 5877 would not have a significant fiscal impact on the state or local units of government.

THE APPARENT PROBLEM:

Automated dispensing systems are drug storage devices or cabinets that electronically dispense medications in a controlled fashion and track medication use. Hospitals have placed these devices at auxiliary or satellite facilities for access by licensed health professionals; the sites have controlled substance additional facility licenses (rather than pharmacy licenses) but are under the control of the central hospital pharmacy.

However, a representative of the Michigan Health and Hospital Association testified before the House Health Policy committee that the Department of Licensing and Regulation informed them last June that these additional facility licenses have been issued in error for several years and are in violation of state law. LARA was made aware of the errors by the U.S. Drug Enforcement Administration (DEA). Reportedly, 13 facilities whose previous licenses were issued in error were denied license renewals in 2016, with an additional 46 facilities to be affected in 2017.

LARA informed licensees that "automated dispensing machines may be legally operated by a pharmacy at a hospital only if there is a licensed pharmacy at the same address . . . In the absence of a licensed pharmacy, a machine may be legally operated at a hospital, or satellite location, under the control of a licensed prescriber" (such as a physician and certain other health care providers).

For example, Spectrum Health testified that its licenses were not renewed in June 2016, and that they were given two options for continued licensure of the additional facilities to comply with state law: (1) to obtain licensure as a pharmacy or (2) to have a prescriber assume control and responsibility of the drugs stored within the machine. Spectrum utilized the second option, but physicians were understandably reluctant to accept control and accountability for the large volume of controlled substances used at these locations.

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Legislation has been proposed that would codify the previous practice that had been utilized (until disallowed by LARA) by rewriting the law so that a pharmacist could legally assume this control and accountability.

THE CONTENT OF THE BILL:

The bill would amend Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to allow a pharmacy that is owned and operated by a hospital to operate an automated dispensing device in another location affiliated with the hospital.

This automated device is under the control and supervision of the pharmacist in charge of the pharmacy, but the pharmacist may delegate the device's stocking, maintenance, removal of medication, and other tasks related to the operation of the device, in accordance with the requirements for delegation and supervision in Article 17. The pharmacist is not required to be physically present to supervise a delegated task.

The operation of the automated device is limited to licensed health professionals. A pharmacy that operates an automated device under this section must notify LARA of the device's location.

Automated device is defined in the bill as a mechanical system that performs an operation or activity, other than compounding or administration, relating to the storage, packaging, dispensing, or delivery of a drug and that collects, controls, and maintains transaction information.

Pharmacy means a facility or part of a facility that is licensed under this part to dispense prescription drugs or prepare prescription drugs for delivery or distribution. Pharmacy does not include the office of a dispensing prescriber or an automated device. For the purpose of a duty placed on a pharmacy under this part, "pharmacy" means the person to which the pharmacy license is issued, unless otherwise specifically provided.

MCL 17702, 17703, and 17707 and proposed MCL 333.17760.

ARGUMENTS:

For:

This bill is necessary, say proponents, because the current options allowed by law for automatic dispensers are inconvenient and outdated.

The bill allows what has been the practice for hospital pharmacies and automatic dispensing devices until the recent notice from state regulators that the law did not allow it. Testimony indicated that existing licenses for "additional facilities" with control by hospital pharmacies are not permitted by current law and had been issued in error. Under current law, these sites would either have to obtain a full pharmacy license or operate under the control of prescribers. This bill would allow what had previously been the practice, with the hospital pharmacy assuming control and accountability.

For:

In addition, some argue that allowing expanded licensing of automated devices would lead to improved availability for patients who live far from a hospital, and allow them to receive their prescriptions in a timelier manner. For example, Mackinac Straits Health System testified that the bill would allow these machines to be placed in outlying clinics (for example, on Mackinac Island or at the Mackinaw City medical practice).

Against:

No one testified or voted against this bill in the House Health Policy Committee.

Legislative Analyst: Jenny McInerney Fiscal Analyst: Marcus Coffin

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