

Notice regarding the use of Automated Dispensing Machines/Devices

May 27, 2016

It has come to Bureau's attention that Hospital Organizations may be operating Automated Dispensing Machines in violation of Michigan law and rule. With assistance from Michigan Health & Hospital Association (MHA) and the Michigan Pharmacists Association (MPA), the Bureau would like to help those organizations achieve compliance without causing an interruption in patient care. Please examine the following and consider what steps your organization should take to achieve or maintain compliance.

- *Is there an automated dispensing machine or device in operation within my healthcare organization?*

What is an automated dispensing device? Michigan's pharmacy rules define it as "a device designed for the specific purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription."¹ These devices are, essentially, storage locations for prescription medication. Some devices may contain patient-specific prescription medication, prepared in advance of placement within the machine. Some contain bulk medication which is sorted and distributed on an as-needed basis. Such devices have seen an increase in use over the last ten years. Some brand names you may recognize for these devices include InstyMeds, ScriptCenter, Omnicell, and Pyxis Medstation.

- *There is an automated device at my hospital. Is it legal?*

That depends where the machine is and who uses and controls the machine. Michigan law requires a prescriber to have a drug control license "for each location in which the storage and dispensing of prescription drugs occur."² The safe storage and dispensing of drugs by a pharmacist is considered the practice of pharmacy, and is required to be done at a location licensed as a pharmacy.³ This means that only dispensing prescribers and pharmacists may use automated dispensing machines, because prescription drugs are stored within them. With one exception outlined below, an automated dispensing machine may be legally operated by a pharmacy at a hospital only if there is a licensed pharmacy at the same address; the machine must be under the control of a licensed pharmacist. In the absence of a licensed pharmacy, a machine may be legally operated at a hospital, or satellite location, under the control of a

¹ Mich Admin Code, R 338.489(1).

² MCL 333.17745(1).

³ MCL 333.17707.

licensed prescriber: a physician, dentist, podiatrist, veterinarian, or optometrist certified to administer and prescribe therapeutic pharmaceutical agents.⁴ The machines cannot be under the sole control of a wholesale distributor, hospital administrative staff, or midlevel prescribers, such as Physician Assistants or Nurse Practitioners.

- *Can Controlled Substances be stored in the machines?*

Yes, so long as the machine is under the control of a prescriber or pharmacy with a valid Michigan controlled substance license at that location. MAPS⁵ reporting is required whenever and wherever controlled substance are dispensed.⁶ If the machine is under the control of a pharmacy, the pharmacist-in-charge (PIC) is responsible for reporting to MAPS. If the machine is under the control of a dispensing prescriber, that prescriber must have a controlled substance license, in addition to the drug control license, and is also responsible for MAPS reporting. The administration, standing alone, of a controlled substance by a prescriber to a patient does not require a drug control license or MAPS reporting.⁷

- *May patients directly access the machine to retrieve medication?*

Not under current regulations. Dispensing is defined in Michigan as the issuance of a drug for subsequent administration to a patient.⁸ Dispensing can only be done at a pharmacy or at the address listed on the drug control license of a dispensing prescriber. The machines may hold presorted patient prescriptions, but they may only be accessed for dispensing by the pharmacist-in-charge, dispensing prescriber, or someone delegated to access them by the dispensing prescriber. See below.

- *If the machines must be under the control of a pharmacy or dispensing prescriber, does that mean that pharmacy technicians or nurses cannot use the machines?*

No. Use of the machines can be supervised and delegated by a prescriber or pharmacist.⁹ The prescriber or pharmacist is not required to be physically present at all times when use of the machine is delegated.¹⁰ Individuals delegated to perform the tasks of a dispensing prescriber or pharmacist should possess sufficient education, training, or experience to perform those tasks.¹¹ Regarding those satellite locations without an onsite pharmacy, dispensing prescribers are further limited by MCL 333.17745b as to whom they may delegate dispensing activities and how much they may dispense.

⁴ MCL 333.17708(2).

⁵ Michigan Automated Prescription System. More information is available at: http://www.michigan.gov/lara/0,4601,7-154-72600_72603_55478---00.html.

⁶ MCL 333.7333a.

⁷ Id.

⁸ MCL 333.17703(2).

⁹ MCL 333.16215(1).

¹⁰ MCL 333.16109(2).

¹¹ MCL 333.16215(1).

- *Do any exceptions to these regulations exist?*

R 338.489(4) prohibits a pharmacy from owning, operating, or controlling an automated dispensing device in a dispensing prescriber's office. This prohibition includes hospitals where dispensing prescribers work. There is one exception to this restriction. Subsection (5) of that rule (and the DEA guidance¹² upon which it is based, referencing retail pharmacy control) allows a pharmacy to own and control an automated dispensing device at a Long Term Care Facility (LTCF), for the purpose of allowing LTCF staff single-dose access to prescription medication at the time of administration to the patient. Subsection (5) of R 338.489 further specifies that these facilities include "any hospital, county medical care facility, nursing home, hospice, or any other skilled nursing facility, as defined in 1978 PA 368, MCL 333.20109 . . ." which houses "registered patients".¹³ This arrangement is designed for dispensing for immediate, in-patient, administration by LTCF staff. The control and delegation of a dispensing prescriber is not required. The pharmacy that owns and stores drugs in the machine is responsible for proper licensure and MAPS reporting. As with any other arrangement in which the machines are used, they are not patient accessible.

- *What steps does my Healthcare Organization need to take to continue to use our automated dispensing machine?*

Closely examine R 338.489 of the Pharmacy General Rules. The Rules can be found on the website of the Office of Regulatory Reinvention at: www.michigan.gov/orr. If there is not a pharmacy licensed at the address the machine is located, the listed exception above notwithstanding, a prescriber will have to assume control and responsibility of the drugs stored within the machine. Not all prescribers are licensed to dispense prescription medication or controlled substances. Get your prescribers the licenses they need at the Bureau's pharmacy webpage: http://www.michigan.gov/lara/0,4601,7-154-72600_72603_27529_27548---,00.html.

¹² Pharmacist's Manual, Section XII – *Other Pharmacy Operations*. Available at <http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/>.

¹³ Mich Admin Code R 338.489(5).