

Pharmacy Law Update for Pharmacists & Technicians
October 1, 2017
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Objectives:

Pharmacist and Pharmacy Technician Learning Objectives:

At the end of this activity, participants should be able to:

1. Describe Advanced Practice Registered Nurse (APRN) and Physician Assistant changes made in their prescribing.
2. Changes to the public health code regarding the use of automated devices.
3. Required training in identifying human trafficking victims for Pharmacy Technicians.
4. Describe the naloxone standing order and the requirements for its use.
5. Describe the changes made for the controlled substance inventory.
6. Describe regulatory changes in 2016 affecting pharmacy.

1. Training in Identifying Victims of Human Trafficking¹

- Pharmacy technician rule already in effect for human trafficking
 - “Beginning with the June 2018 renewal cycle, and all renewal cycles thereafter, licensees must have completed training in identifying victims of human trafficking that meet the standards established in Administrative Rule 338.3659.
 - Licensees, or individuals seeking licensure, must complete training in identifying victims of human trafficking only one time.
 - The department may select and audit a sample of individuals and request documentation of proof of completion of training.”²
- No rule in effect for pharmacists yet

2. Advanced Practice Registered Nurse (APRN)

Who is an APRN³? Means a registered professional nurse who has been granted a specialty certification under section 17210 in one of the following health profession specialty fields

1. Nurse midwife
2. Nurse practitioner
3. Clinical nurse specialist

APRN may prescribe⁴

- Nonscheduled prescription drugs independently
- Controlled substance drugs in schedules 2 to 5 as delegated act of a physician
 - Prescriptions need APRN’s name and physician’s name
 - Prescriptions need APRN’s and physician’s DEA number
- APRN added to the definition of prescriber⁴

3. Physician's Assistant (PA) Changes⁵

- Revised the definition of practice as a physician's assistant
- Added "practice agreement" is a written and signed document meeting the requirements in the Act
- Allows a PA to practice without supervision by entering into a practice agreement with a DO, MD or DPM
- Deleted references to delegation including prescribing of prescription drugs
- Added, "the department, in consultation with the board, may promulgate rules concerning the prescribing of drugs by a physician's assistant"⁵ and the rule may define drugs or classes of drugs that a PA may not prescribe
- PA must obtain a Michigan controlled substance license⁶
- PA added to definition of prescriber⁴

4. Automated Dispensing Devices⁷⁻¹⁰

- The Act added definition for automated device and changed the definition of dispense
- "Automated device" means 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."⁷
- "Dispense" means the preparation, compounding, packaging, or labeling of a drug pursuant to a prescription or other authorization issued by a prescriber."⁸
- Gives permission to "A pharmacy that is owned and operated by a hospital licensed under article 17 may operate an automated device at a location that is affiliated with the hospital but that is not located at the same physical address as the pharmacy."⁹ No other type of pharmacy is mentioned in the Act.
- An automated device is not included in the definition of a pharmacy.¹⁰
- The automated device must be under the control and supervision of the pharmacist in charge (PIC) for the hospital pharmacy
- The PIC according to the requirements for delegation and supervision in article 15 may delegate:
 - the stocking of the automated device
 - the removal of medication from the automated device
 - the maintenance of the automated device
 - other tasks related to the operation of the automated device
 - the PIC is not required to be immediately physically present to supervise a delegated task
- The operation of the automated device is limited to licensed health professionals.

5. Controlled Substance Inventory¹¹

- Conduct inventory between April 1 and June 30 annually
- Change: Do NOT have to send a copy to the Board
- All other requirements remain

6. Naloxone Prescribing and Dispensing Public Act 383 of 2016

- The Act adds to prescription definition: “prescription also includes a standing order issued under section 333.17744e”⁵
- “Notwithstanding any provision of this act to the contrary, a pharmacist may dispense an opioid antagonist to any individual pursuant to a standing order issued by the chief medical executive under subsection (1) and the rules promulgated under this section.”¹²
- Emergency rules are at http://www.michigan.gov/documents/budget/Emergency_Rules_Opioid_Antagonists_572010_7.pdf
- The Act also changed 333.17744b by adding school board to whom a pharmacist may dispense an opioid antagonist¹³

7. Telehealth PA 359 of 2016 & PA 22 of 2017

- Adds definition: “Telehealth” means the use of electronic information and telecommunication technologies to support or promote long-distance clinical health care, patient and professional health-related education, public health, or health administration. Telehealth may include, but is not limited to, telemedicine. As used in this subdivision, “telemedicine” means that term as defined in section 3476 of the insurance code of 1956, 1956 PA 218, MCL 500.3476.¹⁴
- "Telemedicine" means the use of an electronic media to link patients with health care professionals in different locations. To be considered telemedicine under this section, the health care professional must be able to examine the patient via a real-time, interactive audio or video, or both, telecommunications system and the patient must be able to interact with the off-site health care professional at the time the services are provided.”¹⁵
- Adds definition “Telehealth service” means a health care service that is provided through telehealth.¹⁴
- Obtain patient’s consent before providing a telehealth service¹⁶
- May prescribe drugs when providing telehealth service, including controlled substances if requirements are met¹⁷
- Department shall promulgate rules to implement¹⁸

8. Address Opioid Epidemic

Prescription Drug and Opioid Abuse Commission

The Commission will review the Report of Findings and Recommendations for Action from the Michigan Prescription Drug and Opioid Abuse Task Force and develop and propose policies and an action plan to implement the recommendation from the report.

- Updating the Michigan Automated Prescription System
- Increasing licensing sanctions for health professionals who violate prescribing and dispensing practices
- Providing easier access to naloxone

9. Pharmacist in Charge¹⁹

- 333.17748
- Pharmacist in Charge
- Work at least an average 8 hours/week per pharmacy
- Notify Board – 30 days
- Supervise all duties
- Jointly responsible

10. Recent Enforcement Actions of the Board of Pharmacy

- Good faith violations MCL 333.7333
 - MAPS is used to identify licensees to investigate²⁰
- Lack of continuing education
- Dispensing errors
- Sister State actions
- Pharmacy technician discipline

11. DEA allows an unfilled original electronically prescribed controlled substance prescription to be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy.

- Includes all scheduled controlled substances, CII-CV
- Memo was provided by DEA to the National Association of Boards of Pharmacy (NABP).
- Posted on the State of Ohio Board of Pharmacy website.²¹

12. USP <800>

- Effective 1 July 2018

References:

1. Michigan Board of Pharmacy Rules, rule 338.3659 (2016).
2. Pharmacy Technician FAQ [Internet]. Lansing (MI): Department of Licensing and Regulatory Affairs; 2016 [updated 2017 June 20; cited 2017 Aug 1]. Available from: http://www.michigan.gov/documents/lara/Pharmacy_Technician_FAQs_071516_533055_7.pdf.
3. 1978 PA 368, as amended by 2016 PA 449, MCL 333.17211a.
4. 1978 PA 368, as amended by 2016 PA 449, MCL 333.17708.
5. 1978 PA 368, as amended by 2016 PA 379 MCL 333.17048, 333.17548 and 333.18501.
6. Physician's Assistant FAQ's [Internet]. Lansing (MI): Department of Licensing and Regulatory Affairs; [updated 2017 Jan 11; cited 2017 March 25]. Available from: http://www.michigan.gov/documents/lara/Physician_Assistant_FAQs_533445_7.pdf
7. 1978 PA 368, as amended by 2016 PA 528, MCL 333.17702.
8. 1978 PA 368, as amended by 2016 PA 528, MCL 333.17703.
9. 1978 PA 368, as amended by 2016 PA 528, MCL 333.17760.
10. 1978 PA 368, as amended by 2016 PA 528, MCL 333.17707.
11. 1978 PA 368, as amended by 2016 PA 383, MCL 333.7321.
12. 1978 PA 368, as amended by 2016 PA 383, MCL 333.17744e.
13. 1978 PA 368, as amended by 2016 PA 384, MCL 333.17744b.
14. 1978 PA 368, as amended by 2016 PA 359, MCL 333.16283.
15. 1956 PA 218, as amended by 2016 PA 276, MCL 500.3476.
16. 1978 PA 368, as amended by 2016 PA 359, MCL 333.16284.
17. 1978 PA 368, as amended by 2017 PA 22, MCL 333.16285.
18. 1978 PA 368, as amended by 2017 PA 22, MCL 333.16287.
19. 1978 PA 368, as amended by 2015, PA 169, MCL 333.17748
20. Opioid Overprescribing Report For FY 2016 [Internet]. Lansing (MI): Department of Licensing and Regulatory Affairs; [2017 March 1; cited 2017 March 26]. Available from: http://www.michigan.gov/documents/lara/BPL_LARA_Boilerplate_Overprescribing_Report_FY2016_03-01-2017_553553_7.pdf.
21. <http://www.pharmacy.ohio.gov/CStransfer>