Pharmacy Law Update 2014: The Good, the Bad and the Ugly
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Objectives:
At the completion of this program, participants will be able to:
1. Recognize the changes made by the Board of Pharmacy rules effective December 2013.
2. Describe the impact the new laws on pilot projects, auto injectable epinephrine, disclosure, two strikes, no restriction on time for allegations, and override by the department may have on pharmacy practice.
3. Identify requirements for the pharmacist in charge.
4. Describe the potential impact on pharmacy compounding with the passage of the Drug Quality and Security Act and the Michigan compounding legislation.
5. Describe pharmacy functions that require licensure as a pharmacy technician.
6. Identify what is required to participate as a drug disposal site.

Highlights of Recent Board of Pharmacy Rule Changes
1. Licensure
   • Intern hours from 1000 to 1600\(^1\)
   • Updated pharmacist renewal for lapsed license\(^2\,\,4\)

2. Prescription requirements
   • Added to rules\(^5\)
     o Definition for manual signature
   • Deleted from rules\(^6,\,7\)
     o Shall not add handwritten drugs to preprinted form
     o Shall not prescribe noncontrolled and controlled on same form was also dropped from the controlled substances (CS) rule
     o A prescriber shall clearly indicate total number of drugs prescribed on each prescription

3. Pharmacy Record Keeping
   • Paper to electronic records\(^6,\,7\)
     o Added: After 3 years may make an electronic duplicate of the original paper prescription, which then becomes the original prescription
       ▪ Must create a paper copy if requested by Board agent
       ▪ Changes were added to both general rules and CS rules
       ▪ Still keep 5 years (3 paper, 2 electronic)
       ▪ Third party payers may require paper and longer time periods
   • Initialing original prescription\(^8\)
     o A prescription shall be numbered, dated, and initialed or electronically initialed by the pharmacist who performs the final verification of first dispensing
   • Clarified acquisition records could be maintained electronically\(^7\)
   • Clarified invoices could be initialed electronically\(^7\)

4. Prescription Labels and Receipts\(^9,\,10\)
   • Label requirements added
     o Strength
     o Quantity if applicable
     o Name of manufacturer or supplier of drug if no brand name
• Receipts: changed to inclusion of the information in the ADP system constitutes retaining a copy of receipt

5. Controlled Substance Scheduling
• State
  o Updated scheduling of controlled substances (not current with DEA)
  o Bath salts went from emergency rules to permanent rules
• Federal
  o Tramadol schedule IV as of August 18, 2014
  o Hydrocodone containing products schedule II as of October 6, 2014

6. Michigan Automated Prescription System (MAPS) changes
• Report by the end of the next business day all CS data since the previous transmission
• Transmit corrected data to the department within 7 calendar days of being notified of the error

7. Pharmacy requirements
• Electronic versions of references including accessible internet versions
• Electronic versions of the pharmacy laws and rules including accessible internet versions

8. Rescinded rules
• Standard Clinical Thermometer rule 338.488
• Label rule 338.3169
• Fine rule 338.497 but fines remain in the rules covering all health boards

9. Program for Utilization of Unused Prescription Drugs
• Final Rules effective 9-23-2014
• Voluntary program
• No controlled substances
• From eligible facility or manufacturer to pharmacy or charitable clinic
• Drug in original sealed, tamper-evident packaging or unopened unit dose or unit of use packaging
• MCL 333.17775 and 333.17776

Federal Rules
• Disposal of Controlled Substances
  o Pharmacies may participate it is voluntary
  o Modify DEA registration
  o Costly to participate
  o Patients may not return schedule one drugs

Highlights of Recent Law Additions and Changes
1. Pilot Projects Public Act 267 of 2013
• Effective March 30, 2014
• Maximum of 10 pilot projects
• Department may charge a fee
• Department to establish process
• There can be restrictions on pilots
• Department can grant an exception to a rule for the pilot
• Pilot period is 18 months with one extension
• May be required to notify patients affected by the pilot project

2. Dispensing to Other than the Patient (No patient-physician relationship required)
• Auto-injectable Epinephrine Public Acts 186 & 187 of 2013
  o Effective March 14, 2014
  o Pharmacist can dispense to a school board on a prescription from prescriber
  o School board is the patient name
• Opioid Antagonist Public Acts 311, 312 and 313 of 2014
  o Effective October 14, 2014
  o Naloxone hydrochloride or any other similarly acting and equally safe drug approved by FDA for treatment of drug overdose
  o RPh can dispense opioid antagonist to a person or individual other than the patient

3. Over the Counter (OTC) Tax Public Act 211 of 2013
• Effective March 14, 2014
• “The following are exempt from the tax under this act:
  (a) The sale of a prescription drug for human use, an over-the-counter drug for human use pursuant to a prescription, or food or food ingredients, except prepared food intended for immediate human consumption. As used in this subdivision, “prescription” and “prescription drug” mean those terms as defined in section 17708 of the public health code, 1978 PA 368, MCL 333.17708.”

• Effective December 30, 2013 but implementation and enforcement of Article 8 no sooner than 180 days after rescheduling by feds
• Creates new Article 8 Pharmaceutical-Grade Cannabis
• Makes “pharmaceutical-grade cannabis” a Schedule II if authorized by federal authority
• Marijuana currently a federal schedule one

• Effective sometime in 2015 (90 days after adjournment of 2104 Session)
• Department of Community Health and contracted health plans
• MAC pricing reconsideration include 3 NDC codes, if 3 available if not, all
• Available and deliverable by State licensed wholesaler
• Falls into plan’s MAC pricing
• 10 days to complete reconsideration process

6. Public Act 95 of 2014
• Effective July 1, 2014
• Approval of investigation now a 3 member panel, chair and 2 members
• Permits an investigation of an allegation made more than 4 years after an alleged violation
- Effective July 1, 2014
- New law
- Establish conflict of interest disclosure requirements for members of regulatory boards in the Department of Licensing and Regulatory Affairs (LARA).
- Require a board member to abstain from voting on, and refrain from discussing with the board, a matter in which he or she has a conflict of interest.

8. Public Act 97 of 2014
- Effective July 1, 2014
- Removes community service as an option for a Board sanction.
- Adds in 333.16227(1) “For an offense committed within 2 years after a previous offense of the same kind, a disciplinary subcommittee shall suspend the license or registration for a period of at least 180 days or revoke the license or registration.”

- Effective July 1, 2014
- Permit LARA to review a final decision of a disciplinary subcommittee and, under certain circumstances, to set aside the decision.
- Provide that the final action of LARA will as serve the final action on the matter and be subject to judicial review.
- Require LARA to post on its website each final decision in which disciplinary action is taken.

- Effective September 30, 2014
- PIC is new law
- Pharmacist in charge
  - PIC to be licensed in Michigan for a pharmacy
  - PIC and pharmacy will be jointly responsible for compliance
  - May be PIC for more than 1 pharmacy
  - Work an average of 8 hours per week at the pharmacy for which she/he is PIC
  - PIC shall maintain appropriate records and demonstrate compliance upon request of Board
- Notify of change in PIC no later than 30 days
- Supervise the practice of pharmacy for all locations duties include:
  - Supervision of all activities of pharmacy employees as they relate to practice of pharmacy
  - Enforcement and oversight of policies and procedures
  - Establishment and supervision of method and manner for storage and safekeeping of drugs
  - Establishment and maintenance of security provisions to be used when pharmacy is closed
  - Establishment of policies and procedures for individuals who are delegated responsibilities for any of the tasks described in this subsection by the PIC
11. Compounding Laws
   - Federal
     - Drug Quality and Security Act
       - Title I “Compounding Quality Act”22
         - 503A Traditional Compounding
         - 503B Outsourcing Facility
       - Title II Drug Supply Chain Security Act
         - “Outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States”23
         - Development of the system will be phased in over 10-years
         - Certain requirements will start in 2015
   - State
     - Compounding Pharmacy, Public Act 280 of 2014
     - Effective September 30, 2014

Definitions
   - Federal
     - “In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.”24
     - Compounding does not include mixing, reconstituting, or other acts performed with directions in approved labeling
     - Mixing of two or more drugs is compounding24
   - State
     - “Compounding” means the preparation, mixing, assembling, packaging, and labeling of a drug or device by a pharmacist under the following circumstances:
       (a) Upon the receipt of a prescription for a specific patient.
       (b) Upon the receipt of a medical or dental order from a prescriber or agent for use in the treatment of patients within the course of the prescriber’s professional practice.
       (c) In anticipation of the receipt of a prescription or medical or dental order based on routine, regularly observed prescription or medical or dental order patterns.
       (d) For the purpose of or incidental to research, teaching, or chemical analysis and not for the purpose of sale or dispensing.
     - “Compounding” does not include any of the following:
       (a) Except as provided in section 17748c, the compounding of a drug product that is essentially a copy of a commercially available product.
       (b) The reconstitution, mixing, or other similar act that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product.
       (c) The compounding of allergenic extracts or biologic products.”25

12. Compounding
   - Traditional Pharmacy
   - Outsourcing Facility
   - Manufacturer

1. Traditional Compounding24-28
   - Compounding by licensed pharmacist in state licensed pharmacy (federal (f), state (s))
• Compound per prescription for specific patient (f, s)
• Limited quantities before receipt of prescription based on history (f, s)
• Compounded in compliance with USP chapters on pharmacy compounding (f)
• Compounding sterile pharmaceuticals—to be accredited or show compliance with USP standards by September 30, 2015 (s)
• Drug substances used in compounding-use bulk drug substances with USP/NF monograph or a component of a FDA approved drug until final rules (f)
• Cannot compound using bulk drug substances: (f)
  o Withdrawn or removed from market for safety or not effective
  o On “demonstrably difficult” list
• Cannot compound regularly or inordinate amounts “copies” of commercially available products (f)
• Adds extensive record keeping for sterile products (exempts distribution within hospital) (s)
• Shall not offer excess compounded pharmaceuticals to other pharmacies for resale (f, s)
• Shall not distribute samples of compounded pharmaceutical to a health professional (s)
• May advertise or promote the fact that they provide compounding services (f, s)
• Cannot compound and manufacture drug products at same location (s)
• Department may promulgate rules (f, s)
• If provides compounding services must be licensed as pharmacy or manufacturer (s)
• If ships more than 5% across state lines, the state located in has signed a memorandum of understanding (MOU) with FDA
• State Boards to continue oversight and regulation
• State Boards to report to FDA compounding and other violations

2. Outsourcing Facility\textsuperscript{24,26-28}
• FDA registration “voluntary” (FDA may require registration as manufacturer)
• Comply with current good manufacturing practices (CGMP)
• Comply with all FDA requirements (f, s)
• Licensed as a pharmacy in Michigan (no separate license category for outsourcing facility)
• Not required to be licensed as a pharmacy by the FDA
• Compound drugs not commercially available (s)
• Can’t compound copies of drugs unless they are on shortage list (f)
• Compound without a prescription apply to the Department (s)
• May compound sterile products (f)
• Report adverse events regarding compounded products (f, s within 10 days)
• Provide FDA with certain information about the products they compound (f)
• Will be inspected by FDA according to a risk-based schedule
• Labeling requirements and to have statement “This is a compounded drug.” (f)

13. Public Act 280 of 2014\textsuperscript{26-28}
• Requires a pharmacy to notify within 30 days
  o Of a complaint filed by another state
  o An investigation by federal authorities
  o An investigation of an agency into compounding accreditation standards
   • Effective December 22, 2014  
   • Who does any of these functions needs licensure?  
     o Assisting in the dispensing process  
     o Handling transfer of prescriptions, except controlled substances prescriptions  
     o Compounding drugs  
     o Preparing or mixing intravenous drugs for injection into a human patient  
     o Contacting prescribers concerning prescription drug order clarification, which  
       does not include drug regimen review or clinical or therapeutic interpretation  
     o Receiving verbal orders for prescription drugs, except orders for controlled  
       substances  
     o Subject to section 16215, performing any other functions authorized under rules  
       promulgated by the department in consultation with the board  
   • Pharmacy, PIC, and pharmacist responsible that technician is licensed or otherwise  
     authorized to serve as technician  
   • Under supervision and personal charge of pharmacist or dispensing prescriber  
   • 20 hours of continuing education for renewal  
   • “Maintenance of certification is not a requirement for state licensure as a pharmacy  
     technician.”

Types of License  
1. Full license  
   a. Pass certified pharmacy technician exam recognized in act or approved by board  
      or employer based exam approved by board  
   b. Meet all of the requirements of the Act for licensure  
2. Temporary license  
   a. Preparing for the examination  
   b. Expires in 210 days  
3. Limited License  
   a. Employed as technician on effective date at a distinct pharmacy  
   b. Continuously employed since effective date at same pharmacy  
   c. 1000 hours of employment as pharmacy technician during 2 years prior to  
      application  
   d. License is only valid while working for that same pharmacy  
   e. Same pharmacy means a particular pharmacy licensed at a specific location

15. Human Trafficking Training Public Act 343 of 2014  
   • Effective January 14, 2015  
   • By January 14, 2017 rules for training standards to identify victims of human trafficking  

16. “Right to Try” Public Act 345 and 346 of 2014  
   • Effective October 17, 2014  
   • Using a drug that completed Phase I (experimental treatments)  
   • Third parties not required to pay  

References:  
18. 1933 PA 167, as amended by 2013 PA 211, MCL 205.54g.
20. 1978 PA 368, as amended by 2014 PA 97, MCL 333.16227.
27. 1978 PA 368, as amended by 2014 PA 280, MCL 333.17748b.
28. 1978 PA 368, as amended by 2014 PA 280, MCL 333.17748c.
32. 1978 PA 368, as amended by 2014 PA 285, MCL 333.17739c.
Finding Rules and the Public Health Code (PHC) on the Internet

Rules:
Go to www.michigan.gov/lara select “Licensing & Regulation” found on the left hand side then from middle of page “Bureau of Health Care Services” then toward bottom of page “Administrative Rules for Health Boards”. Selecting this will bring up all the rules. Scroll down to Board of Pharmacy and all the Pharmacy rules are listed underneath. This is also where you will find Board of Medicine rules and Board of Osteopathic rules. Selecting those rules will have the rules for delegation of prescribing to physician assistants, nurse practitioners and nurse midwives.

Public Health Code:
Go to www.michigan.gov/lara select “Licensing & Regulation” then “Bureau of Health Care Services” then toward bottom of page “Public Health Code for Health Professions”. This part of the PHC only covers Article 15 Occupations.

For Article 7, the controlled substance section of the PHC, or other articles you will need to follow these steps. Starting with www.michigan.gov select “State Web Site Index” then “Legislature” under Legislative Branch then “Chapter Index” (left side) then “Chapter 333” (scroll down) then “Act 368 of 1978”. This brings up the entire PHC. Here again is Article 15 Occupations, Article 7 Controlled Substances and remaining articles in the PHC.

Looking for a single section in the PHC such as 333.17708 go to www.michigan.gov select “State Web Site Index” under Featured Links, then “Legislature” under Legislative Branch then type in 333.17708 in the box under MCL Section and select search.
Questions:

1. Which of the following is true?
   a. Fines can no longer be levied on a licensee as a discipline.
   b. Rubber stamp signatures are allowed on non-controlled prescriptions.
   c. Internet versions of the Public Health Code and Board rules are now allowed.
   d. MAPS now requires reporting of controlled substance prescriptions dispensed on a weekly basis or every 7 days.

2. A pharmacist can dispense a prescription made out to patient: Lansing School Board, for which of the following?
   a. Glucose tablets
   b. Epinephrine vials
   c. Naloxone injection
   d. Auto-injectable epinephrine
   e. C and D are correct

3. Which of the following is/are true regarding the pharmacist in charge (PIC)?
   a. A pharmacist may be the PIC for more than 1 pharmacy.
   b. A change in PIC must be reported to the department within 30 days.
   c. The PIC must work an average of 8 hours per week at each pharmacy for which they are a PIC.
   d. The PIC and the pharmacy are jointly responsible for the pharmacy’s compliance with the public health code and rules.
   e. All of the above are true.

4. Which of the following is true?
   a. Pharmacies can compound drugs withdrawn from the market.
   b. Pharmacies that compound non-sterile topicals must be accredited.
   c. Outsourcing facilities are required by Michigan to be a state licensed pharmacy.
   d. Compounding pharmacies for sterile products are not required to follow USP standards.

5. A licensed pharmacy technician may do which of the following?
   a. Assist in the dispensing process
   b. Call a prescriber to discuss a drug interaction
   c. Take a verbal controlled substance prescription
   d. Open the pharmacy without the pharmacist present

6. Which of the following is true regarding the DEA drug disposal rule?
   a. Hospital pharmacies may not participate.
   b. Pharmacies to participate must modify their DEA registration.
   c. For pharmacies that do participate there will be no cost to the pharmacy.
   d. Patients may dispose of schedule one drugs at participating pharmacies according to the drug disposal rule.