Pharmacy Law Review & Regulatory Update

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Objectives

• Identify the impact of recent changes to pharmacy laws and regulations
• Identify the common areas of confusion pertaining to pharmacy practice regulations
• Explain the rationale behind current enforcement of pharmacy regulations

Program Overview

1) Review of Recent Regulatory Changes
2) Issue Focus: Controlled Substances
3) Review of Current & Upcoming Regulatory Initiatives
Part I

A REVIEW OF RECENT REGULATORY CHANGES

- SB 704’13 (PA 280’14)
  - Compounding regulations
  - Pharmacist-in-charge definition and responsibilities
- SB 92’13 (PA 285’14)
  - Pharmacy technician licensure requirements
- HB 4736 (PA 525’14)
  - Authorizes expedited partner therapy

SB 704 – Compounding/Pharmacist in Charge (PIC)

Changes Made by this Bill:
- Requires all pharmacies designate a PIC who works at minimum 8 hours per week in the pharmacy (on average).
- Defines the expectations and role of the PIC.
- Legally defines compounding in the state of Michigan.
- Implements certain record keeping requirements and sterility standards for those compounding sterile pharmaceuticals.

SB 704 – Important Questions

- What in MI is considered a “compounding pharmacy?”
- What are the requirements for being accredited as a compounder?
- What about compounding for office use?
  - Michigan Requirements
  - Federal Requirements
SB 704 – Fact & Fiction

• There is NOT a compounding pharmacy license.
• You do NOT have to register with the board of pharmacy to provide prescription specific compounds.
• You DO have to be accredited as being USP 797 compliant to make STERILE compounds.
• The law did not make for office use compounding and copies of commercially available products illegal
  – Federal law already prohibited these practices

Assessment Question ★

1) Which of the following statements are true?
   A. A pharmacy compounding sterile pharmaceuticals will have to apply for a compounding pharmacy license in Michigan
   B. Any pharmacy compounding prescription-specific medications must complete a special registration process with the board of pharmacy
   C. A pharmacy compounding sterile pharmaceuticals must be certified as being USP 797 compliant
   D. Federal law allows for the compounding of prescriptions for office use under FDA 503(A)

Assessment Question ★

1) Which of the following statements are true?
   A. A pharmacy compounding sterile pharmaceuticals will have to apply for a compounding pharmacy license in Michigan
   B. Any pharmacy compounding prescription-specific medications must complete a special registration process with the board of pharmacy
   C. A pharmacy compounding sterile pharmaceuticals must be certified as being USP 797 compliant
      A. This is now a requirement under PA 280 of 2014
   D. Federal law allows for the compounding of prescriptions for office use under FDA 503(A)
PIC responsibilities

333.17748 (5) A pharmacist in charge shall supervise the practice of pharmacy for the pharmacy in which he or she has been designated the PIC. The duties of the PIC include, but are not limited to, the following:

(a) Supervision of all activities of pharmacy employees as they relate to the practice of pharmacy including the purchasing, storage, compounding, repackaging, dispensing, and distribution of drugs and devices to ensure that those activities are performed in compliance with this part and the rules promulgated under this part.

(b) Enforcement and oversight of policies and procedures applicable to the employees of the pharmacy for the procurement, storage, compounding, and dispensing of drugs and the communication of information to the patient in relation to drug therapy.

(c) Establishment and supervision of the method and manner for storage and safekeeping of pharmaceuticals, including maintenance of security provisions to be used when the pharmacy is closed.
PIC responsibilities

333.17748 (5) A pharmacist in charge shall supervise the practice of pharmacy for the pharmacy in which he or she has been designated the PIC. The duties of the PIC include, but are not limited to, the following:

(d) Establishment and supervision of the record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs and devices.
(e) Establishment of policies and procedures

SB 92 – Pharmacy Technician Licensure

Changes Made by this Bill:
• All Pharmacy Technicians must be licensed by June 30, 2015.
• Three Types of Licenses:
  – Full License
  – Limited License
  – Temporary License
• Technician students will not have to be licensed according to the proposed administrative rules for pharmacy technicians.

Functions of the Pharmacy Technician

333.17739 (1)
(A) Assisting in the DISPENSING PROCESS.
(B) HANDLING TRANSFER OF PRESCRIPTIONS, except controlled substance prescriptions.
(C) COMPOUNDING DRUGS.
(D) PREPARING OR MIXING INTRAVENOUS DRUGS for injection into a human patient.
(E) CONTACTING PRESCRIBERS concerning prescription drug order clarification, which DOES NOT INCLUDE drug regimen review or clinical or therapeutic interpretation.
(F) Receiving VERBAL ORDERS for prescription drugs, except orders for controlled substances.
Assessment Question

2) Which of the following is not a function of a pharmacy technician according to MI law?

A. Assisting in the dispensing process
B. Handling transfer of prescriptions (except controlled substances)
C. Compounding drugs
D. Adjudicating prescription claims and other administrative functions

Responsibilities of the Pharmacy

333.17739 (2) A PHARMACY OR DISPENSING PRESCRIBER THAT UTILIZES THE SERVICES OF A PHARMACY TECHNICIAN SHALL ENSURE THAT ALL OF THE FOLLOWING REQUIREMENTS, AS APPLICABLE, ARE MET:

- Technician is licensed
- Technician only performs authorized functions
- Technician is under the supervision of a pharmacist

Assessment Question

3) True or false – A pharmacy technician may only perform their designated functions under the supervision of a licensed pharmacist or dispensing prescriber.

A. True
B. False
Analysis of the Proposed Rules

• Employer-based training programs:
  – Must contain a minimum of 100 questions that cover topics specified in section 17739a(1)(d)(iv) of the code.
  – Application submitted to the department 60 days prior to administering the exam for approval
  – Approval is valid until the examination is changed

Analysis of the Proposed Rules

• Board Approved training programs:
  – A pharmacy technician program accredited by ACPE
  – A pharmacy technician program that is offered by a ACPE accredited pharmacist education program
  – A pharmacy technician training program utilized by a pharmacy or employer that includes specific training in the functions specified in MCL 333.17739(1) required to assist the pharmacist in the technical functions associated with the practice of pharmacy.

Analysis of the Proposed Rules

• Board Approved training programs:
  – Contents of the training program shall include (at minimum)
    • The duties and responsibilities of pharmacy technician and pharmacists:
      – Standards of patient confidentiality and ethics
    • Task and technical skills, policies and procedures related to the technician's position
    • Medical-terminology, abbreviations and symbols commonly used
    • Arithmetic calculations required for the usual dosage determinations
    • Essential functions related to drug purchasing and inventory control
    • Recordkeeping functions related to prescriptions or drug orders
Analysis of the Proposed Rules

- **Pharmacy Technician CE:**
  - No more than 12 hours may be awarded in a 24 hour period
  - Credit will not be awarded for a program that is substantially identical to a program already taken in that renewal cycle
  - 5 credits have to be live
  - Specific subjects:
    - 1 hour of pain and symptom management
    - 1 hour of patient safety
    - 1 hour of pharmacy law
  - Compliance with CE requirements must be documented and retained for 3 years

HB 4736 – Expedited Partner Therapy (EPT)

Changes Made by this Bill:
- Authorized EPT for treatment of sexually transmitted infections, allowing for physicians to prescribe infected individuals and their partners and for pharmacists to fill those prescriptions.
- MPA is working with the Department of Community Health to develop best practice guidelines for the implementation of this practice.

Proposed Provider Guidance

- **Patient’s diagnosis:** Clinical or laboratory diagnosis of chlamydia or gonorrhea.
- **First choice partner management strategy:** Attempt to bring partner(s) in for complete clinical evaluation, STD testing, counseling, and treatment.
- **Appropriate patients for EPT:** Those with partner(s) who are unable or unlikely to seek timely clinical services.
- **Informational materials:** Clear instructions, including contraindications and clinic referrals, should be provided for each partner.
- **Patient Counseling:** Abstinence for seven days after treatment, and until seven days after all partners are treated.
- **Patient Re-testing:** Recommended 90 days after treatment.
**Proposed Provider Guidance**

- If a prescription is provided:
  - Individual prescriptions are given for each partner
  - The prescription, if possible, should be made out in the partner’s name
  - If the partner name is unavailable, the prescription is made to Expedited Partner Therapy
  - In this instance, use January 1 of the current year for the date-of-birth

**Proposed Provider Guidance**

- EPT is NOT recommended for:
  - Men who have sex with men diagnosed with gonorrhea: EPT is not recommended due to the lack of data to demonstrate the effectiveness in this population and the risk of missing STD/HIV co-infections.
  - Patients co-infected with treatable STDs, other than chlamydia or gonorrhea
  - Cases of suspected child abuse or sexual assault
  - Situations where a patient’s safety is in question
  - For partners with known allergies to antibiotics

**Assessment Question**

4) True or false – A prescription issued for Expedited Partner Therapy must indicate the name of the patient who is receiving the prescription.
   - A. True
   - B. False
A final word on liability...

“The EPT legislation the healthcare professional is protected from lawsuits for ordinary negligence but could be student for **gross negligence**. In Michigan, gross negligence is defined as **the willful and wanton disregard of a patient’s welfare**. This is a very high legal standard to meet. In essence it means that the pharmacist would have to have known that it injury would occur in the third-party is the medication or dispensed.”

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**Part II**

**ISSUE FOCUS:**
**CONTROLLED SUBSTANCES**

- Recent DEA Actions
- Frequently Asked Questions
- Prescription References
- Prescription Validity Cases

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**DEA Actions (2013-2014)**

- Movement of Tramadol to Controlled Substance Schedule IV
- Movement of Hydrocodone Containing Products to Controlled Substance Schedule II
- Published final rules on controlled substance take back
Q: Can an optometrist write a prescription for a hydrocodone-containing product?

Q: Can out of state PA’s and NP’s write for controlled substance prescriptions to be filled in MI?

Q: Are stamped signatures valid on controlled substance prescriptions?
Q: We have several patients that are unable to get their full prescription for Subutex and will purchase 1-4 tablets at a time. Does this mean we can only issue 5 fills to the patient, even if they have remaining fills on the prescription?

Q: What are pharmacists allowed to change on a C2 prescription following physician consult?

Q: When can a faxed prescription serve as the original prescription for a C2?
Controlled Substance Schedules

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Prescriptive Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule II</td>
<td>Yes Yes Limited</td>
</tr>
<tr>
<td>Schedule III</td>
<td>Yes Yes Yes</td>
</tr>
<tr>
<td>Schedule IV</td>
<td>Yes Yes Yes</td>
</tr>
<tr>
<td>Schedule V</td>
<td>Yes Yes Yes</td>
</tr>
<tr>
<td>Legend (Unscheduled)</td>
<td>Yes Yes Yes</td>
</tr>
</tbody>
</table>

*Delegating Prescriber’s NAME & DEA must appear on the prescription along with the Midlevel practitioner name & DEA.*

Controlled Substance Schedules

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Valid for...</th>
<th>Maximum Refills</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule II</td>
<td>90 days</td>
<td>0</td>
</tr>
<tr>
<td>Schedule III</td>
<td>6 months</td>
<td>5</td>
</tr>
<tr>
<td>Schedule IV</td>
<td>6 months</td>
<td>5</td>
</tr>
<tr>
<td>Schedule V</td>
<td>1 year</td>
<td>12</td>
</tr>
<tr>
<td>Legend (Unscheduled)</td>
<td>1 year</td>
<td>12</td>
</tr>
</tbody>
</table>

Prescription Signatures

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Written Prescription</th>
<th>Fax to Fax Prescription</th>
<th>Computer to Fax</th>
<th>Computer to Computer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non Controlled</td>
<td>Manual (Wet) Signature</td>
<td>Manual Signature</td>
<td>Electronic Signature*</td>
<td>Electronic Signature</td>
</tr>
<tr>
<td>CIII-V</td>
<td>Manual Signature</td>
<td>Manual Signature**</td>
<td>Not Allowed</td>
<td>Electronic Signature</td>
</tr>
<tr>
<td>CII</td>
<td>Manual Signature</td>
<td>Manual Signature**</td>
<td>Not Allowed</td>
<td>Electronic Signature</td>
</tr>
</tbody>
</table>

* Only when sent directly from computer to fax electronically. If possible AVOID THIS. The prescription cannot be printed and then faxed because it considered a fax-to-fax prescription. Although this is allowed by law, this form of transmission is prohibited under Medicare Part D for all prescriptions for those beneficiaries.

** Only allowed for home-bound patients on injectable CII narcotics, if the patient is in a nursing home, or if the patient is in a home hospice facility.
**Signature Requirements (Revised)**

<table>
<thead>
<tr>
<th>Prescription Type</th>
<th>Signature Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written Prescription</td>
<td>Manual or “Wet” signature</td>
</tr>
<tr>
<td>Phone Prescriptions</td>
<td>No signature necessary*</td>
</tr>
<tr>
<td>Facsimile Prescriptions</td>
<td>Manual or “Wet” signature</td>
</tr>
<tr>
<td>Electronic Prescriptions</td>
<td>Electronic signature**</td>
</tr>
</tbody>
</table>

* Pharmacy personnel are responsible for properly identifying the prescriber
** Prescriptions are only electronic if they REMAIN electronic. Once a prescription is printed, it is now considered a written prescription.

**Assessment Question**

5) True or false – Since rescheduling, Nurse Practitioners are never allowed to issue prescriptions for Hydrocodone containing products.
   A. True
   B. False

**Case 1:**

A physician prepares a prescription for Norvasc for a patient subsequent to a recent office visit. The prescriber prepares and sends the prescription electronically, but it is not received by the appropriate pharmacy. The physician’s agent prints off the prescription and faxes it to the pharmacy.

Is this prescription valid, or invalid?
Case 2:
A physician assistant prepares a prescription for Norco 5-325 and faxes it to the pharmacy. The physician assistant has appropriate controlled substance prescribing authority via licensure and delegation and includes all necessary prescription elements on the fax.

Is this prescription valid, or invalid?

Case 3:
A osteopathic physician prepares a prescription for Oxycontin and faxes it to the pharmacy with the stipulation this is an emergency situation for a patient who currently resides at home. No additional follow up is conducted with the patient or the pharmacy.

Is this prescription valid, or invalid?

Case 4:
A physician faxes a prescription for morphine to the pharmacy for delivery to a home-hospice patient covered by the hospice benefit under Medicare.

Is this prescription valid, or invalid?
Case 5:
A pharmacy contacts the physician’s office regarding a patient’s prescription written for Suboxone, #30, 5 refills issued 3 months ago. The patient has been picking up the prescription in quantities of 7, and the pharmacy is asking for a new prescription because they have issued 6 fills of #7 under the current prescription.

Is this prescription valid, or invalid?

Case 6:
A patient drops off an otherwise valid prescription for Vicodin 10-300, quantity 30, at the pharmacy on Monday. An hour later, he returns to the pharmacy and the pharmacist explains that they only had 10 tablets in stock. The patient picks up the 10 tablets at that time and then returns Friday and picks up the remaining 20 tablets.

Is this prescription valid, or invalid?

Case 7:
A patient is appropriately diagnosed with ADHD and is maintained on Adderall XR once daily. The physician issues the patient 3 prescriptions, dated 4/2/15, 5/2/15, and 6/2/15. Each prescription is for a 30 day supply.

Are these prescriptions valid, or invalid?
Part III
A REVIEW OF CURRENT LEGISLATIVE INITIATIVES

- Biosimilar Substitution
- Pharmacy Reimbursement
- Open Pharmacy Networks
- Provider Status
- Legislation and Policies Introduced this Session

Biosimilar Substitution

**The Issue:** The ability of pharmacists to interchange biosimilar products at the point of sale.

**Our Position:** Pharmacists should be able to make substitutions for originator biologic products at the point of sale only if the FDA has deemed the products to be interchangeable without prescriber notification.

**The Controversy:** Not all biosimilar products are deemed interchangeable by the FDA. Some groups feel that substitution of biosimilars should be accompanied with physician notification.
**Pharmacy Reimbursement**

**The Issue:** Pharmacies continue to struggle with reimbursement rates that are below their acquisition costs for multiple medications.

**Our Position:** Pricing schedules (such as Maximum Allowable Cost or MAC lists) should be updated in a regular/timely manner to reflect market drug prices.

**Current Status:** Waiting to see the effects of SB 656 of 2013.

**Next Steps:** Document any situations in which MAC price appeals continue to be denied without appropriate rationale.

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**Open Pharmacy Networks**

**The Issue:** Network exclusions and preferred networks continue to interfere with the patient’s ability to utilize the pharmacy of their choosing.

**Our Position:** Patients on government sponsored health plans should have the opportunity to participate with any pharmacy of their choosing without suffering cost disincentives such as increased copayments.

**Stipulations:** Pharmacies must be able to meet the plan’s terms and conditions (including meeting preferred network reimbursement levels and plan specified performance standards).

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**Provider Status**

**The Issue:** Pharmacists are currently not classified as providers under the Social Security Act.

**Our Position:** With the potential of their being a shortage of primary care providers in the near future, pharmacists could be key to ensuring that patients receive the appropriate care.

**Where the Issue is Now:** Legislation has been reintroduced at the federal level in BOTH the House and the Senate.
6) If the Pharmacist Provider Status legislation introduced at the federal level is passed in its current form, which of the following services will a pharmacist be able to provide to recipients in medically underserved areas?
   A. Medication therapy management
   B. Medication reconciliation as part of the transitions of care
   C. Disease state management interventions
   D. All of the above
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