Objectives

1. Identify the changes that have occurred in healthcare and pharmacy regulations in 2015-2016
2. Describe the impact of recent regulatory changes on patients and providers
3. Identify continuing advocacy efforts being pursued by the Michigan Pharmacists Association

Areas of Focus

Pharmacy Compounding
Epinephrine Access
Opioid Abuse & Controlled Substances
Victims of Human Trafficking
Pharmacy Technician CE Requirements
Expedited Partner Therapy
Biosimilar Substitution & Notification
NECC Compounding Crisis¹

September 2012

- Dr. April Pettit finds fungus in the spinal fluid of one of her patients. Contacts Tennessee Department of Health. This is one of the first patients to be discovered as part of the larger outbreak.
- Tennessee Department of Health reaches out to the CDC.
- Source of the outbreak narrowed down to vials of contaminated methylprednisolone produced by the New England Compounding Center (NECC)
- FDA begins to be involved in the investigation.
- NECC recalls three lots of the injectable product (roughly 17,000 vials)
NECC Compounding Crisis

October 2012
- More than 60 cases of fungal meningitis are reported nationwide.
- NECC recalls all products produced by the company in 2012. Shuts down operations.
- FDA investigation discovers visibly unsanitary conditions at NECC.

November 2012
- 480 people in 19 states are diagnosed with fungal meningitis; more than 30 of these patients die as a result of the illness.

Drug Quality and Security Act of 2013

- Introduced Sept. 27, 2013 by Rep. Fred Upton
- Signed by President Obama on Nov. 27, 2013
- Makes significant alterations to current compounding regulations differentiating compounding activities into two categories:
  - 503(A) Compounding
  - 503(B) Compounding

MI Public Act 280 of 2014

- Introduced Dec. 3, 2015 by Senator Joe Hune
- Signed by Governor Snyder on July 16, 2014
- Introduced more accountability to the pharmacy regulatory scheme
- Mandated accreditation of pharmacies producing sterile compounds as being USP 797 compliant by an entity approved by the Board of Pharmacy
Proposed Revisions to Pharmacy General Rules

- Identifies two entities as board approved for USP 797 compliance assessment:
  - Pharmacy Compounding Accreditation Board (a service of the Accreditation Commission for Health Care)
  - National Association of Boards of Pharmacy – Verified Pharmacy Program
- Eliminates the 5% rule
- Applies to all pharmacies – including health systems
- Deadline for compliance: Sept 30, 2016

**EPINEPHRINE ACCESS**

Epinephrine in Schools\(^2,3\)

- A movement to have schools stock epinephrine for administration to students accelerated in 2011 following the deaths of two students – one in Illinois, one in Virginia
- President Obama signed the School Access to Emergency Epinephrine Act on November 13, 2013 which provides financial incentive for schools to stock epinephrine.
Epinephrine in Schools\textsuperscript{2,3}

- Prescribers issue prescriptions in the name of the school board. Pharmacies are authorized to dispense.
- Public Act 221, 2015 expands this to any authorized entity – effective March 16, 2016.

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**OPIOID ABUSE AND CONTROLLED SUBSTANCES**
Approaches to Addressing the Opioid Abuse Epidemic
• Governor’s Opioid Task Force Recommendations
• Increasing Naloxone Access
• MAPS Reporting Requirements
• Civil Liability for Protection for Refusing to Dispense Opioids

West Virginia Addiction Case
• Defendants:
  – TUG VALLEY PHARMACY, LLC;
  – B & K PHARMACIES, INC. d/b/a FAMILY PHARMACY;
  – STROSNIDER DRUG STORE, INC. d/b/a SAV-RITE PHARMACY;
  – DR. DIANE SHAFER
  – West Virginia Supreme Court of Appeals
• 29 Plaintiffs in Mingo County, WV
• May 13, 2015
• Determined that providers issuing controlled substances can be held liable if a patient develops addition

IDENTIFYING VICTIMS OF HUMAN TRAFFICKING
New Requirement in MI Law

333.16148 – (1) ...By 2 years after the effective date of the amendatory act that added this sentence, the department shall promulgate rules to include training standards for identifying victims of human trafficking required for individuals licensed or registered under this article, except those licensed under part 188 or subject to section 17060. The training standards for identifying victims of human trafficking shall apply for a license or registration renewal beginning with the first renewal cycle after the rules are promulgated and for an initial license or registration issued 5 or more years after the rules are promulgated.

Training Must Cover...

- Understanding the types and venues of human trafficking in the United States
- Identifying victims of human trafficking in health care settings
- Identifying the warning signs of human trafficking in health care settings for adults and minors
- Resources for reporting the suspected victims of human trafficking

Acceptable providers or methods of training:

- Training offered by a nationally-recognized or state-recognized health-related organization.
- Training offered by, or in conjunction with, a state or federal agency.
- Training obtained in an educational program that has been approved by the board for initial licensure or by a college or university.
- Reading an article related to the identification of victims of human trafficking that meets the requirements of the law and is published in a peer review journal, health care journal, or professional or scientific journal.
To prove you have completed training:

• An individual must be able to produce:
  – Proof of completion certificate issued by the training provider
  – A self-certification statement by an individual containing:
    • The date, training provider name, and name of training
    • The title and author of an article, publication name where the article was published

PHARMACY TECHNICIAN CE REQUIREMENTS

Continuing Education Requirements

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<thead>
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<th>If you were licensed...</th>
<th>Then you need...</th>
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<tbody>
<tr>
<td>Prior to June 30, 2015</td>
<td>10 hours of CE</td>
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<tr>
<td>After June 30, 2015</td>
<td>0 hours of CE</td>
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For renewal after a complete two year licensure period.

<table>
<thead>
<tr>
<th>Continuing Education</th>
<th>Number of Hours</th>
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<tbody>
<tr>
<td>Total Hours</td>
<td>20 hours</td>
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<tr>
<td>Live Hours</td>
<td>hours</td>
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<tr>
<td>Pain and Symptom Mgmt</td>
<td>1 hour</td>
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<tr>
<td>Patient Safety</td>
<td>1 hour</td>
</tr>
<tr>
<td>Pharmacy Law</td>
<td>1 hour</td>
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</table>
EXPEDITED PARTNER THERAPY (EPT)

MCL 333.5110
Expedited partner therapy
- A prescriber may issue treatment to the partner of a patient with a diagnosis of a sexually transmitted infection
  - Chlamydia & Gonorrhea only
- May be written for any number of partners within the 60 days prior to diagnosis
- Partner must be unlikely to seek treatment
- Written prescription may be issued anonymously, with “EPT” as the patient name

BIOSIMILAR SUBSTITUTION AND NOTIFICATION
HB 4812 as passed out of the House

- Biosimilar substitution & notification
- Dispenser must notify the prescriber by either:
  - Making an entry in an interoperable medical record
  - Through the use of electronic prescribing technology
  - Through the use of a pharmacy benefits management system
  - Through the use of a pharmacy record electronically accessible by the prescriber
  - By facsimile, telephone, electronic transmission or other prevailing means.

Notification Stipulations

- Would not apply to
  - Products where there is no interchangeable alternative
  - Refills where the same drug product is dispensed
- Would be required
  - For the initial fill on any biologic product with an interchangeable alternative
  - Is not contingent on substitution

QUESTIONS?
Self Assessment

1) Changes to which of the following regulatory areas have been passed or implemented since the end of 2014?
   a) Pharmacy Technician
   b) Epinephrine Access
   c) Sterile Compounding Accreditation
   d) All of the above

2) As of February, 2016, the date for all facilities compounding sterile products must be in the process of being accredited by a board of pharmacy approved entity by
   a) July 1, 2016
   b) July 30, 2016
   c) September 1, 2016
   d) September 30, 2016
Self Assessment

2) As of February, 2016, the date for all facilities compounding sterile products must be in the process of being accredited by a board of pharmacy approved entity by
   a) July 1, 2016
   b) July 30, 2016
   c) September 1, 2016
   d) September 30, 2016

Self Assessment

3) Which of the following entities have been approved as accrediting organizations for USP 797 compliance by the MI Board of Pharmacy?
   a) PCAB
   b) NABP-VPP
   c) TJC
   d) Two of the above

Self Assessment

3) Which of the following entities have been approved as accrediting organizations for USP 797 compliance by the MI Board of Pharmacy?
   a) PCAB
   b) NABP-VPP
   c) TJC
   d) Two of the above
Self Assessment

4) As passed out of the House of Representatives, HB 4812 classifies appropriate dispensing notification for biosimilars as including:
   a) Entry into an interoperable health record
   b) Entry into an online database that is physician accessible
   c) Phone calls
   d) All of the above

References