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GOVERNOR

STATE OF MICHIGAN  
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS  
LANSING

SHELLY EDGERTON  
DIRECTOR

## MICHIGAN BOARD OF PHARMACY APRIL 11, 2018 MEETING

### APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, as amended, the Michigan Board of Pharmacy met on April 11, 2018, at the Ottawa Building, Conference Room 3, 611 West Ottawa Street, Lansing, Michigan 48933.

#### CALL TO ORDER

Nichole Cover, R.Ph., Chairperson, called the meeting to order at 10:01 a.m.

#### ROLL CALL

**Members Present:** Nichole Cover, R.Ph., Chairperson  
Patricia Keim, R.Ph., Vice-Chairperson  
Cynthia Boston, BHS, R.PhT.  
David Hills, Public Member  
Suit Hing Moy-Sandusky, R.Ph.  
Kathleen Pawlicki, MS, FASHP  
Jonathan Pignataro, Public Member (left at 11:57 a.m.)  
James Stevenson, PharmD  
Mary Ann Victor, JD, Public Member

**Members Absent:** Kathleen Burgess, Public Member

**Staff Present:** Andria Ditschman, Analyst, Boards and Committees Section  
Kimberly Gaedeke, Acting Deputy Director, LARA  
Kiran Parag, Analyst, Compliance Section  
Cheryl Pezon, Acting Director, BPL  
Rick Roselle, Analyst, Boards and Committees Section  
Michele Wagner-Gutkowski, Assistant Attorney General  
Stephanie Wysack, Board Support, Boards and Committees Section

#### APPROVAL OF AGENDA

MOTION by Keim, seconded by Moy-Sandusky, to approve the agenda as presented.











Larry Wagenknecht from the Michigan Pharmacists Association spoke regarding the bona fide prescriber-patient relationship rule.

Kathleen A. Reed, JD, of Dykema Gossett PLLC, spoke regarding the bona fide prescriber-patient relationship rule.

## **ANNOUNCEMENTS**

The next regularly scheduled meeting will be held June 13, 2018, at 10:00 a.m. at the Ottawa Building, 611 West Ottawa Street, Upper Level Conference Center, Conference Room 3, Lansing, Michigan.

## **ADJOURNMENT**

MOTION by Hills, seconded by Pawlicki, to adjourn the meeting at 12:37 p.m.

A voice vote followed.

MOTION PREVAILED

Minutes approved by the Board on June 13, 2018.

Prepared by:  
Stephanie Wysack, Board Support  
Bureau of Professional Licensing

April 16, 2018



# NABP

National Association of Boards of Pharmacy

## NABP Programs and Services:

Michigan Board of Pharmacy  
April 2018





# National Association of Boards of Pharmacy<sup>®</sup>

- **501(c)(3) charitable and educational organization**
  - **Founded in 1904**
- **Member boards of pharmacy** for 50 states, District of Columbia, and United States territories.
- **NABP's mission is to assist member boards in public protection.**
  - License transfer program
  - Examinations
  - Accreditations

NABP



## Examinations



## Accreditations



## Assessments



## Licensure



## Member Services

*Eligibility Service*

*HIPDB  
NABPLAW*

*Inspection  
Blueprint  
Program*

## Consumer Protection



# NABP



# NABP

National Association of Boards of Pharmacy

## Non-Resident Licensure-Post NECC

*NABP Multistate Pharmacy Inspection Blueprint Program*

*NABP Verified Pharmacy Program (VPP)*

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# Multistate Pharmacy Inspection Blueprint Program

- Provides the various tools needed to ensure that member boards can inspect resident sterile compounding pharmacies that ship across state lines:
  - Consistent set of inspection criteria developed by the state boards
  - Universal Inspection form developed by NABP to blueprint standards
  - Compounding inspection training provided for state inspectors
- Participating states will help develop a national standard for inspections that will further safeguard interstate pharmacy compounding practice





# What Is an Inspection Blueprint?

- Created in 2014 following a universal request from member boards to increase inspection consistency across the states following the NECC disaster
- Minimum set of agreed upon areas/items that boards believe should be addressed at the time of inspection
- 42 states represented at initial Inspection Blueprint workshop
- Universal Inspection Form
  - 7 states piloted and reviewed form





# Inspection Blueprint Program

- A “Blueprint state” must agree to the following requirements for conducting inspections of **sterile compounding pharmacies that ship across state lines**:
  - Utilize the Universal Inspection Form or their state form that is cross-walked to the Blueprint (USP 795/797)
  - Inspectors who conduct sterile compounding inspections will have initial training:
    - CriticalPoint Sterile Compounding Boot Camp, NABP and CriticalPoint Sterile Compounding Inspector Training
  - Compliance officers will participate in annual webinar training to be offered at no cost by NABP
  - Inspection frequency for sterile compounding pharmacies that ship across state lines is no less than once every 18 months
  - Share their inspection reports through the Verified Pharmacy Program inspection sharing network (Unless prohibited by state law)



# Current Blueprint Landscape

- 12 States have signed participation agreements:
  - KY, LA, OH, NJ, ND, SD, TN, VA, WV, and WY, MS, NC
  - 9 are using the universal form
  - OH, NJ, NC using their own cross-walked form
  
- 11 additional states are in various stages of gaining approval to sign agreement or have state inspection form cross-walked to the blueprint standards.
  
- 14 states are in earlier stage of review of the program
  
- New grant available for in-state sterile compounding inspection training



# NABP Verified Pharmacy Program

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# Verified Pharmacy Program



- The Verified Pharmacy Program (VPP) was developed to fill the gaps in the nonresident pharmacy system and provide states complete information needed to make licensing decisions
- Extrapolate the successes of the Electronic Licensure Transfer Program<sup>®</sup> for pharmacists and apply it to facilities that want to operate in multiple states
- Create an NABP e-Profile for each pharmacy and link to e-Profiles for key pharmacy personnel
- Create an inspection clearinghouse to facilitate the sharing of inspection reports/results



# VPP – A Unified Resource for States



- Verify pharmacy licenses (resident/non-resident)
- Verify pharmacist-in-charge (PIC) licenses
- Verify that a qualified inspection has occurred, either by the resident state in accordance with the established uniform standards, or by NABP
- Report any disciplinary action by another state
- Perform on-site inspection if required
- All information will be packaged through VPP
  - accessible on Board e-Profile Connect interface

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# VPP Utilization by States

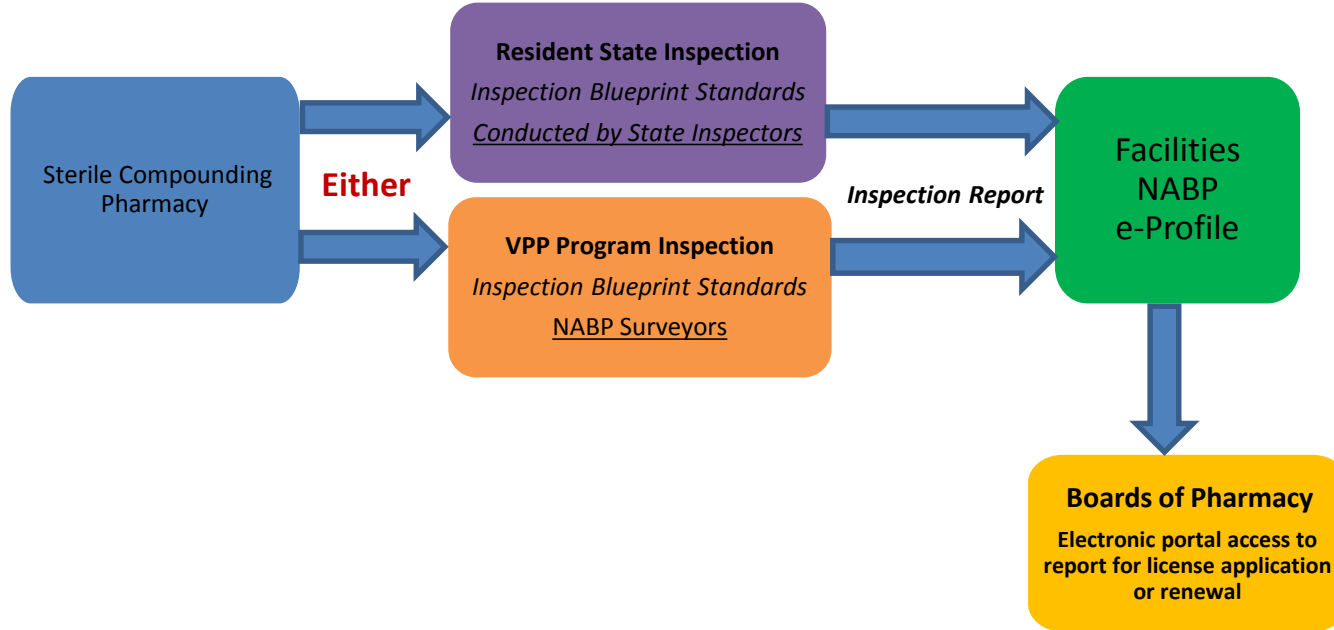


- 46 states utilize VPP in some manner
- Required by Virginia for non-resident sterile compounding pharmacies, if resident state inspection can not show compliance with USP Chapter 797
- Utah requires a VPP inspection or resident board inspection to blueprint standards for all non-resident compounding pharmacies within 2 years of application.
- Approved inspection entity by regulation or policy in CO, IA, FL, KS, LA, NC, ND, OH, PA, and TX



# Assisting State Licensing Decisions:

## Inspection Blueprint Program/ Verified Pharmacy Program





**NABP**

National Association of Boards of Pharmacy

# Michigan Project



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# VPP

- VPP = Verified Pharmacy Program
- SSR (site survey report)- items taken directly from the Multistate Pharmacy Inspection Blueprint.



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# Michigan Resident Inspections



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# VPP Process for MI

- Pharmacy receives a letter that they are included in the project
- Each has an e-profile number and will submit information via the VPP portal
- Timeline for inspections will be set
- Pharmacies divided geographically into East, West and North.
  - Chosen Based on Risk levels (Types of compounding, amounts, out-of-state)
- Inspections will be unannounced.





# State of Pharmacy Practice in Michigan

- High volume of high-risk pharmacies
  - 80 inspections in 2017
    - Hospital/Institutional – 64%
    - Retail – 28%
    - Long-term care – 5%
    - Veterinary - 18%
    - Nuclear – <1%





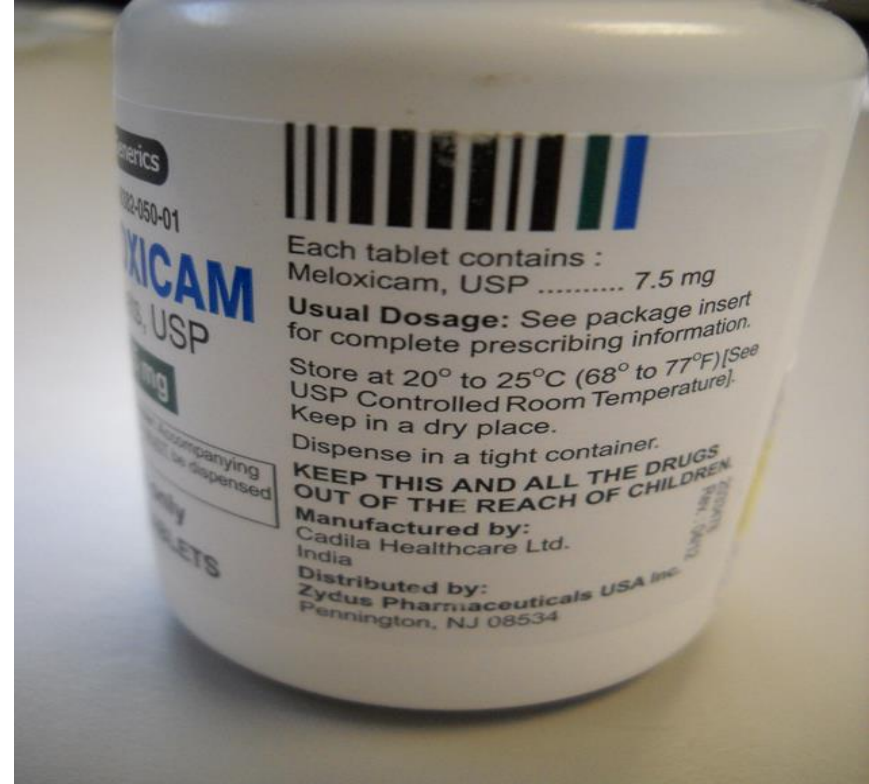
# Michigan Pharmacy General Overview

- 88% of pharmacies inspected held an accreditation or certification.
- 70% performed NS compounding (43% HD)
- 88% performed ST compounding (86% HD)
  - 94% Low; 89% Medium; 13% High Risk
- 48% of pharmacies stated purchasing compounded products from other entities for dispensing to patients.



# Michigan Pharmacy Findings – 2017 examples

- Improper temp/humidity monitoring – Not 24/7; No max/min; No plan for excursions.





# Michigan Pharmacy Findings – 2017 examples

- Using term “expiration date” versus BUD
- Certifications of ISO rooms and PECs performed at REST
- Sprinkler heads not flush with the ceiling; ledges in ISO areas including viewing windows
- Pressure gauges not calibrated annually
- Return ducts located in the ceiling
- No smoke testing of rooms and/or PECS



# Michigan Pharmacy Findings – 2017 examples

- Personnel not garbed correctly – wearing makeup, jewelry, fingernail polish, hair not under head cover.





# Michigan Pharmacy Findings – 2017 examples

- Handwashing – not using nail picks; using brushes which are not permitted.





# Michigan Pharmacy Findings – 2017 examples

- Missing COAs on media/APIs
- ACDs not used in Media Fill
- Hazardous compounding in the same area as nonhazardous compounding and room not under negative pressure.
- Batches not marked as hazardous.



# Michigan Pharmacy Findings – 2017 examples

- Preparations not being checked against a light and dark background for particulates







# Michigan Pharmacy Findings – 2017 examples

- Lack of understanding of first air
- No genus determination of CFUs
- Lack of understanding of certification reports
- Sparse training documentation
- Improper room type for High Risk Compounding





# Our patients are important

We must ensure  
both safe  
compounds and a  
secure drug supply  
chain.



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# Future Initiatives

- Continuing pharmacy inspections (phase two)
  - Utilizing VPP for non-resident pharmacies
- Wholesaler distributors
  - Identifying and Inspecting
- NAPLEX and MPJE Eligibility Processing
- Data exchange and integration
  - NABP e-Profile
- Compliant intake and investigations





# Thank you



# NABP

# **PHARMACY CONTINUING EDUCATION REVIEW**

## **April 11, 2018**

### **APPROVED PROGRAMS**

**ST. JOHN RETAIL PHARMACIES** –St. John Retail Pharmacy USP 800 Compliance Plan held on various dates and locations for 1 hour.

**RECOMMENDATION BY MARY SANDUSKY**

**ST. JOHN HOSPITAL AND MEDICAL CENTER, DEPARTMENT OF INPATIENT SERVICES**

–Lets Get Personal- A Preview of Precision Medicine held on March 20, 2018 in Detroit, MI for 1 hour.

**RECOMMENDATION BY MARY SANDUSKY**

**ST. JOHN HOSPITAL AND MEDICAL CENTER, DEPARTMENT OF INPATIENT SERVICES**

–Pharmacoeconomics: Economic Theory and Clinical Practice held on March 13, 2018 in Detroit, MI for 1 hour.

**RECOMMENDATION BY MARY SANDUSKY**

**MIDMICHIGAN MEDICAL CENTER-MIDLAND PHARMACY DEPARTMENT** –Antibiotic Dosing Strategies held on various dates in Midland, MI for 1 hour. (For Pharmacists)

**RECOMMENDATION BY MARY SANDUSKY**

**MIDMICHIGAN MEDICAL CENTER-MIDLAND PHARMACY DEPARTMENT** –Antibiotic Dosing Strategies held on various dates in Midland, MI for 1 hour. (For Pharmacy Technicians)

**RECOMMENDATION BY MARY SANDUSKY**

**MUNSON MEDICAL CENTER CANCER SERVICES- COWELL INFUSION PHARMACY-** 2018 Oncology Pharmacy Lecture Series held on April 21, 2018 in Traverse City, MI for 4 hours.

**RECOMMENDATION BY MARY SANDUSKY**

**SPECTRUM HEALTH DEPARTMENT OF PHARMACY-** Nexus Pharmacy Education- Pharmacy Technician held on various dates and locations for 4 hours.

**RECOMMENDATION BY MARY SANDUSKY**

**SPECTRUM HEALTH DEPARTMENT OF PHARMACY-** Nexus Pharmacy Education- Pharmacy Med History Technician held on various dates and locations for 4 hours.

**RECOMMENDATION BY MARY SANDUSKY**

**SPECTRUM HEALTH DEPARTMENT OF PHARMACY-** Nexus Pharmacy Education- Pharmacist held on various dates and locations for 16 hours.

**RECOMMENDATION BY MARY SANDUSKY**

**ST JOHN HOSPITAL AND MEDICAL CENTER, DEPARTMENT OF INPATIENT SERVICES-** Sickle Cell Disease and Pain Management held on April 11, 2018 in Detroit, MI for 1 hour.

**RECOMMENDATION BY MARY SANDUSKY**

**PROMEDICA CONTINUING MEDICAL EDUCATION DEPT-** 11<sup>th</sup> Annual Pharmacology Update: A Practical Guide for Physicians and Allied Healthcare Professionals held on March 17, 2018 in Toledo, OH for 6 hours.

**RECOMMENDATION BY MARY SANDUSKY**

**DENIED PROGRAMS**

**N/A**

**PENDING PROGRAMS**

**N/A**