

RICK SNYDER

STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

SHELLY EDGERTON

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.

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A roll call was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Keim, Cover

Nays: None

MOTION PREVAILED

APPROVAL OF MINUTES

MOTION by Pawlicki, seconded by Stevenson, to approve the February 14, 2018 meeting minutes as written.

A roll call was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Keim, Cover

Nays: None

MOTION PREVAILED

NABP PRESENTATION

Gaedeke introduced Neal Watson and Duann Thistlethwaite from the National Association of Boards of Pharmacy (NABP). They presented a PowerPoint entitled "NABP Programs and Services:" (Please see addendum #1)

REGULATORY CONSIDERATIONS

Robia Baydoun, R.Ph. – Petition for Reinstatement

MOTION by Hills, seconded by Keim, to deny the Petition for Reinstatement.

Discussion was held.

A roll call was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Keim, Cover

Nays: None

MOTION PREVAILED

Naresh Kumar Jain, R.Ph. – Proposal for Decision - Reinstatement

MOTION by Stevenson, seconded by Moy-Sandusky, to accept the Proposal for Decision and grant reinstatement of Petitioner's license to a limited license for a minimum of two years to practice under the general supervision of a fully licensed, board-approved pharmacist. Terms of the limitation prohibit Petitioner from owning, investing in, or having any ownership or investment interest in a pharmacy. Petitioner is required to petition for reclassification of the limited license. Petitioner is placed on

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probation to run concurrent with the period of limitation with quarterly supervisor reports. The period of limitation and probation shall be reduced only while Petitioner is practicing as a pharmacist in Michigan and complying with the Public Health Code.

Discussion was held.

A roll call was taken: Yeas: Boston, Hills, Pawlicki, Stevenson, Victor, Cover

Nays: Moy-Sandusky, Pignataro, Keim

MOTION PREVAILED

OLD BUSINESS

Compounding Applications

Joint Commission/Home Care Program – Sterile Compounding Accreditation Organization

MOTION by Boston, seconded by Hills, to untable from August 9, 2017.

A voice vote followed.

MOTION PREVAILED

Discussion was held.

MOTION by Stevenson, seconded by Moy-Sandusky, to table the application for further information.

A roll call vote was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Keim, Cover

Nays: None

MOTION PREVAILED

CHAPs - Reconsideration

MOTION by Stevenson, seconded by Moy-Sandusky, to deny the request for reconsideration.

Discussion was held.

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A roll call vote was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Cover

Nays: None Recuse: Keim

MOTION PREVAILED

TDS - Reconsideration

MOTION by Stevenson, seconded by Pignataro, to table the request for reconsideration to review additional documentation provided.

Discussion was held.

A roll call vote was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Cover

Nays: None Recuse: Keim

MOTION PREVAILED

Internship Application

May Al-Sayab

MOTION by Boston, seconded by Keim, to untable from February 14, 2018.

A voice vote followed.

MOTION PREVAILED

MOTION by Boston, seconded by Pawlicki, to deny the request for Internship.

A roll call vote was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Keim, Cover

Nays: None

MOTION PREVAILED

Pharmacy Technician Program/Examination Application

McLaren Oakland Inpatient Pharmacy

MOTION BY Victor, seconded by Hills, to untable from February 14, 2018.

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A voice vote followed.

MOTION PREVAILED

MOTION by Victor, seconded by Stevenson, to approve the Pharmacy Technician Program and examination.

A roll call vote was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Keim, Cover

Nays: None

MOTION PREVAILED

NEW BUSINESS

Resolution Presentation

Cover presented the Resolution to Nabil Fakih, R.Ph. honoring his time served as a member of the Board of Pharmacy.

HPRP Annual Report

Roselle presented the Health Professional Recovery Program (HPRP) October 1, 2016 through September 30, 2017 Annual Report and discussed program participation and statistics.

Pharmacy Technician Program/Examination Application

Kings Pharmacy

MOTION BY Pawlicki, seconded by Keim, to approve the Pharmacy Technician Program and examination.

A roll call vote was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Keim, Cover

Nays: None

MOTION PREVAILED

Continuing Education Review

Moy-Sandusky directed the Board to the list of continuing education programs for consideration. (See Addendum #2).

MOTION by Boston, seconded by Victor, to approve the continuing education programs.

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A roll call vote was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Keim, Cover

Nays: None

MOTION PREVAILED

Rules Discussion

Ditschman presented the proposed Draft rules (see addendum #2).

Discussion was held.

MOTION by Moy-Sandusky, seconded by Hills, to approve the Draft rules as presented.

A roll call vote was taken: Yeas: Boston, Hills, Moy-Sandusky, Pawlicki,

Pignataro, Stevenson, Victor, Keim, Cover

Nays: None

MOTION PREVAILED

Chair Report

Cover informed the Board that great things are happening within the department and that she is excited about Senate Bill 801.

Cover informed the Board that she and Boston will be attending the NABP 114th Annual Meeting from May 5 - 8, 2018. Gaedeke and Pezon will also be attending as Michigan will be presented with the 2018 Fred T. Mahaffey Award.

Department Update

None.

PUBLIC COMMENT

Paige Fults from the Michigan Health & Hospital Association spoke regarding the bona fide prescriber-patient relationship rule.

Nabil Fakih, R.Ph. thanked the Board for their great work while he served on the board. He stated that he has all the confidence that the board will continue to do a great job protecting the public health, safety, and welfare.

Barry Cargill from the Michigan HomeCare & Hospice Association spoke regarding the bona fide prescriber-patient relationship rule.

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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®

- 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



Examinations



Accreditations

Assessments



Member Services







Eligibility Service









HIPDB NABP*LAW*











Inspection **Blueprint Program**





Consumer Protection







NABP

National Association of Boards of Pharmacy

Non-Resident Licensure-Post NECC

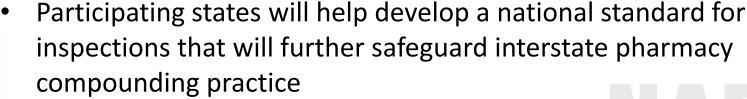
NABP Multistate Pharmacy Inspection Blueprint Program

NABP Verified Pharmacy Program (VPP)



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







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 pew grant available for in-state sterile compounding inspection training





NABP Verified Pharmacy Program

NABP



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® 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





VPP Utilization by States

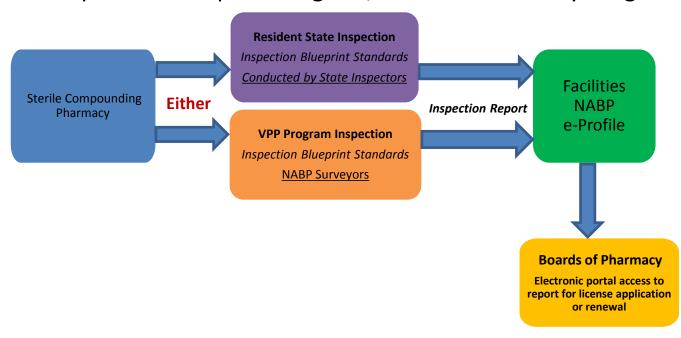


- 46 states utilize VPP in some manner
- Required by Virginia for non-resident sterile compounding pharmacies, if resident state inspection can not show compliance with USP Chapter 797
- ➤ Utah requires a VPP inspection or resident board inspection to blueprint standards for all non-resident compounding 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



NABP

National Association of Boards of Pharmacy

Michigan Project





VPP

VPP = Verified Pharmacy Program

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





Michigan Resident Inspections



NABP



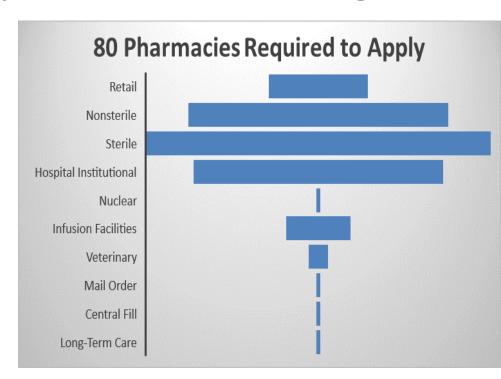
VPP Process for MI

- 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 highrisk pharmacies
 - 80 inspections in 2017
 - Hospital/Institutional 64%
 - Retail 28%
 - Long-term care 5%
 - Veterinary 18%
 - Nuclear <1%



NABP



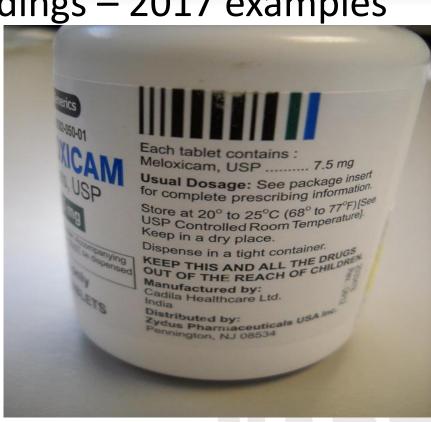
Michigan Pharmacy General Overview

- 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.

NABP



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





- 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





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





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





NABP



- 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.





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



NARP



- 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.









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



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 PHARMCY 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-** 11th 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