MICHIGAN BOARD OF MEDICINE

July 18, 2018 MEETING

APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, the Michigan Board of Medicine met on July 18, 2018 at the Ottawa Building, Conference Room 3, 611 West Ottawa Street, Lansing, Michigan 48933.

CALL TO ORDER

Mohammed Arsiwala, MD, Chairperson called the meeting to order at 10:13 a.m.

ROLL CALL

Members Present: Mohammed Arsiwala, MD, Chairperson
Louis Prues, Public Member, Vice Chairperson
Richard Bates, MD
Michael Chafty, MD (Left at 12:05 p.m.)
Stacey Frankovich, Public Member (Left at 11:55 a.m.)
Michelle Gormas, PA
Renee Johnston, Public Member
Cara Poland, MD
Venkat Rao, MD
James Rogers, MD
Traci Ruiz, Public Member
James Sondheimer, MD
Paul Sophiea, Public Member
Dennis Szymanski, MD
Shereen Tabrizi, Public Member
Rosalie Tocco-Bradley, MD, PhD (Left at 10:55 a.m.)

Members Absent: Michael Chrissos, MD
Eric Stocker, Public Member
Terri Tahnoose, Public Member

Staff Present: Weston MacIntosh, Analyst, Boards and Committees Section
Kiran Parag, Analyst, Compliance Section
LeAnn Payne, Board Support, Board and Committees Section
Michele Wagner-Gutkowski, Assistant Attorney General
Arsiwala Introduced Cara Poland, MD as a new professional member to the Board.

**APPROVAL OF AGENDA**

MOTION by Rogers, seconded by Sophiea, to approve the agenda as presented.

A voice vote followed.

MOTION PREVAILED

**APPROVAL OF MINUTES**

MOTION by Szymanski, seconded by Johnston, to approve the May 16, 2018 minutes, as presented.

A voice vote followed.

MOTION PREVAILED

**Drug Enforcement Presentation**

Cathy Gallagher and Leigh Ann Halas from the Drug Enforcement Administration presented on “Diversion Control: Combating the Supply”, addressing the opioid abuse epidemic in Michigan (Addendum #1).

**OLD BUSINESS**

None

**NEW BUSINESS**

**REGULATORY CONSIDERATIONS**

**Judith Cooper Andersen Berk, MD – Petition for Reinstatement**

MOTION by Sophiea, seconded by Gormas, to discuss.

Sondheimer recused himself.

A voice vote followed.

MOTION PREVAILED

Discussion was held.
MOTION by Szymanski, seconded by Chafty, to accept the Petition for Reinstatement and place Petitioner on probation for one year, with the following terms: Petitioner must contact HPRP within 30 days and enter into a disciplinary regulatory monitoring agreement. Petitioner must also contact and enroll with the Center for Personalized Education for Professionals (CPEP) for a reentry clinical assessment of her professional skills and knowledge and comply with any CPEP recommendations. Failure to comply with the terms of the Order shall result in license suspension.

A roll call vote followed: Yeas: Bates, Chafty, Gormas, Johnston, Poland, Rao, Sophiea, Szymanski, Tabrizi, Prues, Arsiwala
Nays: Frankovich, Rogers, Ruiz
Recuse: Sondheimer

MOTION PREVAILED

Mark Kallaway, MD – Proposal for Decision

MOTION by Gormas, seconded by Rao, to discuss.

Bates recused himself.

A voice vote was held.

MOTION PREVAILED

Discussion was held.

MOTION by Rao, seconded by Johnston, to accept the Proposal for Decision and grant reinstatement to a limited license. Petitioner's license is limited for one day not to exceed one year. During the limitation, the Petitioner shall not engage in the practice medicine until he provides evidence to the Department of completing a reentry clinical assessment by CPEP with focus on anesthesiology, pain management and addiction medicine, and has been endorsed safe to practice by CPEP. Upon receipt by the Department of a satisfactory CPEP assessment and safety to practice endorsement, the Petitioner's limited license shall automatically be reclassified to a full and unlimited license status. Upon reclassification, Petitioner’s shall be placed on probation for one year. During the probationary period Petitioner shall contact HPRP within 30 days and enter into a disciplinary regulatory monitoring agreement and continue to comply with any CPEP recommendations. In addition, Petitioner shall complete a total of 45 hours of live continuing education with 15 hours in each of the following areas: anesthesiology, pain management, and addiction medicine. Failure to comply with the terms of the Order shall result in license suspension.

A roll call vote followed: Yeas: Chafty, Gormas, Johnston, Poland, Rao, Sondheimer, Sophiea, Szymanski, Tabrizi, Prues, Arsiwala
Nays: Frankovich, Rogers, Ruiz
Recuse: Bates

MOTION PREVAILED
FSMB Update

Arsiwala informed the Board that he attended the FSMB training for new FSMB Board members and that Cheryl Pezon, the Bureau Director, attended training for new Executive Directors.

Monitoring Guidelines for Peer Review Reports

Arsiwala explained the process of Peer Review Reports. He informed the Board that he is developing a universal reporting template to assist in helping the process be more consistent.

Expert Reviewers

Arsiwala informed the Board of the need for more expert reviewers in many specialties. He advised members to email MacIntosh or himself with recommendations.

Chair Report

Activity from March 14th to June 30, 2018

Conferee assignments  2
Quarterly Reports Approved  4
CME/CPEP Courses approved  16
Face to Face Conferee  4
Settlement offers, and conferee conference issued  22
Violation of consent orders and suspension issued  1
Emergency Suspension issued  3
File Review  6
Physician Reviewer approved  2

Department Update

MacIntosh informed the Board that the Department has issued 1 special volunteer license since the last meeting.

MacIntosh announced that Cheryl Pezon has been named the Director of the Bureau of Professional Licensing.

MacIntosh announced that Kim Gaedeke has been named Deputy Director of the Department of Licensing and Regulatory Affairs (LARA).

Parag introduced Michael Draminski as the new Compliance Manager and Carla Chapman as the new analyst in the Compliance Section.
MacIntosh introduced Dawn Gage, Licensing Manager, Debi Haigh, Senior Analyst, and Justine Foy, Departmental Technician as the medicine profession licensing team.

COMMITTEE REPORTS

Investigations and Complaints

Rogers reported that the Investigations and Complaints Committee reviewed one hundred eight (108) files in June 2018. Sixty (60) files were authorized for investigation and forty-seven (47) files were closed. One (1) file was returned for additional records. There were three (3) reviewers.

The Investigation & Complaints Committee reviewed forty-seven (47) files in July 2018. Seventeen (17) files were authorized for investigation and thirty (30) files were closed. There were three (3) reviewers.

Arsiwala announced he appointed Cara Poland to the Investigations and Complaints Committee.

Rules Committee

MacIntosh informed that the Board the rules committee is still working on the rule set and has met twice since the last meeting.

Disciplinary Subcommittee

Johnston reported that the Disciplinary Subcommittee (DSC) met today and considered thirty-nine (39) matters: four (4) Administrative Complaints, two (2) Proposals for Decision, Twenty-six (26) Consent Orders and Stipulations, and seven (7) Requests for Dismissal.

PUBLIC COMMENT

Dr. Grace Jacek from the University of Detroit Mercy introduced herself to the Board and informed them that she brought a student with her to observe the meeting.

ANNOUNCEMENTS

The next regularly scheduled meeting will be held September 19, 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 Sondheimer, seconded by Sophiea, to adjourn the meeting at 12:15 p.m.

A voice vote followed.

MOTION PREVAILED

Minutes approved by the Board on: September 19, 2018.

Prepared by:
LeAnn Payne July 20, 2018
Bureau of Professional Licensing
Active Registrants
1,722,526* total (nationwide)

Michigan Registrant Population
(52,125 registrants)

- Manufacturers: 16
- Distributors: 22
- Practitioners: 37,746
- NPs/PAs: 10,441
- Pharmacies: 2,579
- Opioid Treatment Programs: 41
- DATA-Waived Practitioners: 1,210*

The CSA's Closed System of Distribution
Maintaining the CSA's Closed System of Distribution

Methods of Drug Diversion

How Does DEA Combat Diversion?
### State Ranking* - OxyContin
**January - December 2017**

<table>
<thead>
<tr>
<th>State</th>
<th>Prescriptions</th>
<th>Opioids Prescribed</th>
<th>OxyContin Prescribed</th>
<th>Pain Management Prescribed</th>
<th>Total Prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>1234</td>
<td>1234</td>
<td>1234</td>
<td>1234</td>
<td>1234</td>
</tr>
<tr>
<td>NY</td>
<td>1234</td>
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<td>1234</td>
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</tr>
</tbody>
</table>

*Note: State abbreviations are used for confidentiality.

### State Ranking* - Methadone
**January - December 2017**

<table>
<thead>
<tr>
<th>State</th>
<th>Methadone Prescribed</th>
<th>Total Prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>1234</td>
<td>1234</td>
</tr>
<tr>
<td>NY</td>
<td>1234</td>
<td>1234</td>
</tr>
</tbody>
</table>

*Note: State abbreviations are used for confidentiality.

### Medication-Assisted Treatment
**Federal Requirements**

- **Registration:**
  - State (OTP)
  - DEA
  - Dispensing (methadone, buprenorphine)

- **Recordkeeping:**
  - Accountability

- **Registration:**
  - Medical Board
  - LARA
  - DEA

- **Process:**
  - Apply to CSMT
  - DEA waiver
  - DEA issues DR

- **Recordkeeping:**
  - Prescription requirements
  - Accountability
Obtaining a DATA Waiver: Physicians

- Under Drug Addiction Treatment Act of 2000 (DATA 2000), qualified physicians may apply for waivers to treat opioid dependency with approved buprenorphine products in any setting in which they are qualified to practice.
- A "qualified physician," as defined by DATA 2000, is:
  - Licensed under state law
  - Registered with DEA to dispense controlled substances
  - Required to treat more than 30 patients at a time within the first 30 days
  - Certified by training and/or certification.
- To maintain a waiver, a physician must also be capable of referring patients to counseling and other services.

DATA Waivers

- Approximately 1.5% of Michigan practitioners are DATA-waived.
- Learn more about buprenorphine and how to qualify for a physician waiver at:
  - https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver

Obtaining a DATA Waiver: NPs and PAs

- The Comprehensive Addiction and Recovery Act (CARA) extends buprenorphine prescribing privileges to office-based settings to qualified NPs and PAs until October 1, 2021.
- NPs and PAs must complete 24 hours of required training and can treat up to 30 patients.
- NPs and PAs may send copies of their training certificates to SABHSA at 357774 P.O. Box 410, Topeka, KS 66633.
- SAMHSA forwards waiver applications to the DEA, which will assign the NP or PA a special identification number. All buprenorphine prescriptions for opioid dependency treatment must include this specialized number.
Obtaining a DATA Waiver

SAMHRA requires a waiver for

DEA assigns a special identification number in addition to a physician's regular DEA number

Individual physician can apply to treat

- Year 1 register 10 patients
- Year 2 register 50 patients
- Year 3 renewal approval

DEA Application and Renewal

Registrants

Registrant is a term used to describe an individual or business entity that holds a DEA registration number authorizing the handling of controlled substances and/or List 1 chemical products.

Combined, they are often referred to as the regulated community.
Mid-Level Practitioners

Under the Controlled Substances Act (CSA), the term "mid-level practitioner" (MLP) means an individual practitioner other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the licensed State or jurisdiction in which he or she practices, to dispense, administer, and prescribe a controlled substance in the course of professional practice.

Examples include:

- Nurse Practitioner
- Physician Assistant
- Certified Registered Nurse Anesthetist
- Oral Surgeon
- Hospital Pharmacist
- Optometrist
- Optician
- Doctor of Chiropractic
- Doctor of Podiatric Medicine
- Doctor of Podiatric Osteopathy
- Psychologist
- Dietitian
- Dentist
- Dentist Anesthetist
- Veterinarian
- Veterinary Medical Technologist or Technician
- Veterinarian Anesthetist

Registration with DEA is not required for a MLP who only administers controlled substances on behalf of a registered practitioner or along the activity as at the practitioner’s presence.

Separate Registrations for Separate Locations

CFR 1301.12:

A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

Obtaining Applications

  (only 225, 263, & 519 applications can be downloaded)
  DEA Form 224 and 234s cannot be downloaded.
- PAPER FORMS: obtained by calling 800-882-0539 or by writing to:
  DEA Headquarters
  Attn: Registration Section/ODR
  PO Box 2639
  Springfield, VA 22152-2639
Application for Registration

CFR 1301.13

- Applications may be submitted anytime.
- Applicant must receive approval and certificate before engaging in business.
- Renewal applications: accepted within 60 days of expiration for most registrants. Bulk manufacturers and importers may renew within 120 days of expiration.
- Registration period
- Registration fees

Application for Registration

www.deadiversion.usdoj.gov

Modification in Registration

CFR 1301.51

Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address by submitting a letter of request to the Registration Unit, DEA.

- Letter must include: registrant's name, address, and registration number as printed on the certificate of registration, and the substances and/or schedules to be added to his/her registration or the new name or address.
- Letter shall be signed in accordance with Sec. 1301.13(q).
- Mailing addresses can be found in Sec. 1327.01.
Renewal Applications

- Mailed 60 days prior to expiration of current registration
- Mailed to bulk manufacturers 120 days prior to expiration of current registration
- If registrant does not receive renewal application within 45 days of expiration date, registrant must notify, in writing, the Registration Unit of the Administration at the address previously noted.

Secure and Responsible Drug Disposal Act of 2010

Sources of Supply
### Medicine Cabinets: Easy Access
- More than half of teens (73%) indicate that it is easy to get prescription drugs from their parent's medicine cabinet.
- Half of parents (55%) say anyone can access their medicine cabinet.
- Almost four in 10 teens (38%) who have misused or abused a prescription drug obtained it from their parent's medicine cabinet.

### Patient Education
- **Monitor:**
  - Place drug strips in your home.
  - Keep track of what is taken.
  - Control drug prescribed to teens.
  - NEVER share.
- **Safeguard:**
  - Properly dispose of unused or expired medicine.
- **Dispense:**
  - Secure prescription for safety.
  - Some medicines are physically you know about.

### Why Security and Disposal Matter
- Approximately 60,000 emergency room visits are due to accidental medication overdoses.
- Prescription drugs can be misused to get high.
- Can lead to development of clini, substance abuse disorder.
- Primary source: medicine cabinets.
- Intentional misuse:
  - Medications are prescribed on a per-patient basis; sharing is never safe.
  - The safety or ingredients of shared medications cannot be guaranteed.
Resources for Drug Disposal

- DEA Diversion website: www.deadiversion.usdoj.gov (click “Drug Disposal Information,” then “Search for an Authorized Collector Location”)
- Rx Drug Drop Box: www.rxdrugdropbox.org
- Dispose My Meds: www.disposeyneds.org
- U.S. Food and Drug Administration: www.fda.gov (search “disposal”)

Collection Receptacle Locations

- Pharmacies
- Long-Term Care Facilities
- Hospitals/clinics
- Opioid Treatment Programs
- Police Departments

Search for a disposal location online at www.deadiversion.usdoj.gov/pdfs/disposal

Disposal for Practitioners

- Promptly destroy controlled substance in accordance with 21 CFR § 317.60(a) using an on-site method of destruction
- Promptly deliver controlled substance to a DEA-registered reverse distributor by common or contract carrier, pick-up or by reverse distributor pick-up at the registrant’s registered location
- For returns or recalls, promptly deliver controlled substance to the registrant from whom it was obtained, the registered manufacturer of the substance, or other registrant authorized by the manufacturer to accept returns/ recalls on manufacturer’s behalf
- Respect assistance from the Special Agent in Charge of the Administration in the area where the practitioner is located
360-Degree Strategy

Three-pronged approach:

**Diversion Control**
A three-pronged approach: Diversion Control

**Law Enforcement**
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**Community Outreach**

Community Partnerships

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Registrant Outreach Initiatives

- Physician training
- Pharmacy outreach initiative

Comments / Questions?

Contact Information

- Complaints
  - Local Police: Immediate threats to human health/safety
  - Consumer complaints: LARA: 517-373-9978
  - DEA: http://www.dea.gov
  - DEA: Report prescription drug diversion by doctor/pharmacy
  - www.dea.gov/oas/collect.htm
  - HHS: Hotline 1-800-HHS-TIPS, HHS.HIPPS.gov/report fraud
- State PDMP
  - Michigan Automated Prescription System (MAPS) help: www.michigan.org/no-passinfo
- Recovery
  - 1-800-662-HELP (4357)
  - https://michigan.com/no-passinfo