



Iowa Board of Pharmacy

July 14, 2021 Minutes

Members Present

Brett Barker, Chair
Gayle Mayer, Vice-Chair
Erik Maki
Jim Mennen
Joan Skogstrom
Kathy Stone
Sherill Whisenand

Mitchell Barnett, Associate Director of PMP
Laura Steffensmeier, Assistant Attorney General
Melissa Carstens, PMP Associate Administrator
Becky Carlson, IMP3 Case Manager
Jonathan Resch, Pharmacist-Intern

Members Absent

Dane Nealson

Compliance Officers

Sue Mears
Jim Wolfe
Dan Sedlacek
Mark Mather
Christie Carlson
Curtis Gerhold
Jennifer Tiffany
Jean Rhodes

Staff Present

Andrew Funk, Executive Director
Therese Witkowski, Executive Officer
Amanda Woltz, Administrative Assistant

Call to Order

At 9:02 a.m., on Wednesday, July 14, 2021, Brett Barker, called the meeting of the Iowa Board of Pharmacy to order.

Public Comment Period

No comments

Approval of Minutes

1. May 12, 2021 Open Session Minutes

Motion by Kathy Stone, second by Sherill Whisenand, to approve the Open Session Minutes of the May 12, 2021 meeting as presented. Motion passed unanimously.

Requests

1. Request for credit for health-related graduate studies pursuant to 657 IAC 2.12(6)“a” – Laura Arensdorf, Pharmacist License 17656, Ankeny

Motion by Gayle Mayer, second by Kathy Stone, to grant credit up to 10 hours of continuing education for pharmacist Arensdorf's graduate program for each of the renewal periods that end June 30, 2021 and June 30, 2023. Motion passed unanimously.

2. Request to extend current waiver of 657 IAC 2.4(2) requiring a licensure candidate to pass both examination components within one year – Mariam Wanis, Pharmacist-intern Registration 7169, Coralville

Motion by Gayle Mayer, second by Sherill Whisenand, to approve the request to September 1, 2022. Motion passed unanimously.

3. Request to waive 657 IAC 17.3(1)“c” requiring evidence of drug distributor accreditation – Reliance Wholesale Inc., Wholesale Distributor License 6414 (cancelled 12/31/2020), Collierville, TN

Motion by Kathy Stone, second by Sherill Whisenand, to deny the request. Motion passed unanimously.

4. Request to waive 657 IAC 13.11(1) requiring a technician complete 1,000 hours of training in an Iowa pharmacy – Renue Rx #9, Pharmacy License 1681, Bancroft

Petition withdrawn.

Petition for Exemption from the Mandate for Electronic Transmission of Prescriptions

1. Allergy Partners of Cedar Rapids

Motion by Kathy Stone, second by Joan Skogstrom, to approve the exemption to September 30, 2021. Motion passed unanimously.

2. Dr. Renee Lass, DO

Motion by Sherill Whisenand, second by Joan Skogstrom, to deny the request. Motion passed unanimously.

License/Registration Applications

1. Pharmacist License Applicant – Jill Smith, Georgetown, KY

Motion by Gayle Mayer, second by Joan Skogstrom, to offer the applicant licensure by consent agreement. Motion passed unanimously

Reports & Informational Items

1. Executive Director's Report

Rotation Student:

- Drake P4 student Jonathan Resch is finishing his rotation with the Board. Jonathan will be graduating from Drake in 2022 with a dual degree in pharmacy and business administration. David Bainbridge with the University of Iowa will be starting his rotation with the Board on Monday, July 26, 2021.

Staffing:

- Deborah McClure has joined Board staff as the licensing specialist for pharmacy licensing.
- Dakota Waltz has joined Board staff as the licensing specialist for pharmacy technicians.
- Compliance officer Jim Wolfe received his 50 year pharmacist certificate.
- Compliance officer Dan Sedlacek has announced his retirement. Dan's last day with the Board will be Friday, September 3. Dan is also celebrating 5 years of service with the Board.

Staff Anniversaries:

- Administrative Assistant Amanda Woltz has been with the state for 18 years and with the Board for the past 4 years.
- Licensing Specialist Melanie Givens has been with the Board for 2 years.

Nominations and Appointments:

- Jim Mennen was appointed to the Board and began serving July 1, 2021. He is currently employed with Hy-Vee as the director of pharmacy compliance.
- Compliance officer Sue Mears was appointed to serve as a member of the NABP Model Act Review Committee. This committee convened virtually on July 12 to review the NABP Model Act and will have subsequent meetings in the future.

FDA MOU

- At its most recent meeting, the Rules Committee considered rules written in response to the Board's legislation that will lay the groundwork necessary for the Board to comply with its duties set forth by the FDA MOU which addresses certain aspects of human drug compounding. Those rules will be up for consideration and NOIA later on in the agenda. The FDA has provided states with a year-long deadline to sign the MOU (originally it was a 6 month deadline), which expires on October 27, 2021. The FDA intends to begin enforcing the 5% limit described in section 503A of the FDCA on interstate distribution of human drug compounds by pharmacies in states that have not signed the MOU by the deadline. On April 27, 2021, NABP sent a request to FDA to extend the deadline for states to sign the MOU (thus extending the enforcement deadline) but did not include a specific time frame for the extension. NABP cited COVID-19 and state legislature's frequency of meetings as the main reason for the request. To date, a response has not been provided by FDA.

NABP Annual Meeting-Passed Resolutions

- State Boards of Pharmacy Response to Pandemics and Other Natural Disasters (Resolution 117-1-21)
- Work Group to Consider Permanently Extending Certain Waivered Provisions (Resolution 117-2-21)
- State Boards of Pharmacy Oversight of Drug Importation (Resolution 117-3-21)
- Task Force on Workplace Safety and Well-Being (Resolution 117-4-21)
- Task Force on Safety-Sensitive Measures to Review Medication Errors (Resolution 117-5-21)
- Recognition Resolution (Resolution 117-6-21)

2. Meetings and Travel

- Practice Act Modernization Town Hall Meeting (virtual)

July 21, 2021

- NABP District V Meeting (Virtual) August 6, 2021
- Practice Act Modernization Town Hall Meeting U of I College of Rx August 11, 2021
- Practice Act Modernization Town Hall Meeting Drake University August 24, 2021
- Next Board meeting August 31-September 1, 2021

3. 50 Year Pharmacists

- Paul Bickel
- Roland Brand
- Kevin Clark
- Judson Conner
- Gerald Dunn
- Mark Edwards
- Steven Garrett
- Dennis Harker
- Dennis Jorgensen
- Daniel Kopp
- Michael Lewis
- Kenneth Manley
- Rex McKee
- Denny Miller
- Robert Nolan
- David Post
- Barbara Potter
- Robert Sample
- Duane Schmaltz
- James Schumacher
- Alan Shepley
- Leo Smith
- Janet Swanson
- Jack Vallandingham
- James Vandevanter
- Karr VanNordstrand
- Joseph Winston
- James Wolfe
- Janet Zeitler

4. Legal Update

Laura Steffensmeier provided a legal update. Empower Pharmacy has filed an appeal to the Board's decision in case 2018-0123. A decision is expected by the end of the year or spring of 2022.

5. Prescription Monitoring Program (PMP) Update

Mitch Barnett provided a program update. Mitch and the Board's Administrative intern, Emily Albers, presented PMP data at the 117th Annual NABP meeting. Emily was also mentioned in the recent issue of NABP Innovations.

- Over 600 entities have integrated with the PMP, 470 of which are new.
- PMP update tracks overlapping opioid and benzodiazepine use.
- Rule Changes – Schedule V (CV) prescriptions are required to be reported to the PMP. This took effect May 12, 2021 and educational efforts are continuing to expand.
- Pharmacist Narcan® Dispensing Program – continues to grow.
- Disposal Kit Dispensing – 303 fills for 301 patients across a wide geographical range.
- Integration Funding – 29 entities accepted continued funding for a second year, and 18 new entities were added. A total of 470 Iowa providers are newly integrated.
- PMP Associate Director presented at IDPH's SPF Rx in June and IPA's 2/2/2 Webinar in July.

6. Board-Sponsored Medication Disposal Program Update

Melissa Carstens reported that disposal has stayed consistent from last month. The program has gained four new sites.

7. Iowa Monitoring Program for Pharmacy Professionals (IMP3) Update

Becky Carlson provided a program update. The program has a total of 19 participants. The program will be switching drug screening to First Source Solutions, to be more user-friendly and cost-effective.

8. Compliance Report

Christie Carlson provided a compliance update. Compliance staff will be transitioning to a new inspection style. Since the May Board meeting compliance officer have conducted 87 inspections and completed 28 investigations. The compliance team have recently met with new DEA staff. Jean Rhodes and Christie Carlson completed sterile compounding investigator training.

Rules and Legislation

1. Vote on amended Statewide Protocols
 - a. Naloxone
 - b. Nicotine-replacement tobacco cessation
 - c. Immunization

Motion by Sherill Whisenand, second by Gayle Mayer, to approve the Statewide Protocols as presented. Motion passed unanimously.

2. Proposed for Emergency Adoption and Notice of Intended Action to amend Chapter 3, "Pharmacy Technicians," to provide minimum standards for technician immunization administration

This rule making provides the minimum training requirements for pharmacy technicians to engage in the administration of vaccinations. Currently, under the national emergency declaration and PREP Act in response to the global coronavirus pandemic, pharmacy technicians are authorized, pursuant to training and continuing education requirements, to administer pediatric vaccinations to any patient aged three to 18 years old and COVID vaccinations to patients of any age for which the vaccination is authorized or approved. This rule making identifies properly trained technicians so that such technicians may engage in pharmacist-delegated vaccine administration under the board's statewide protocol for immunizations and not be limited to pediatric or COVID vaccinations.

Motion by Gayle Mayer, second by Sherill Whisenand, to emergency adopt and file for Notice of Intended Action. Motion passed unanimously.

3. Proposed for Notice of Intended Action to amend Chapter 10, "Controlled Substances," to add four substances to the Iowa Controlled Substances Act and three List I chemicals as Precursor Substances

Motion by Kathy Stone, second by Gayle Mayer, to file for Notice of Intended Action. Motion passed unanimously.

4. Proposed for Notice of Intended Action to amend Chapter 3, "Pharmacy Technicians," Chapter 8, "Universal Practice Standards," Chapter 20, "Compounding Practices," and Chapter 39, "Expanded Practice Standards," to implement House File 514 relating to technician trainee registration renewal, compounding data reporting, and pilot projects and Senate File 296 relating to statewide protocols

Motion by Kathy Stone, second by Erik Maki, to file for Notice of Intended Action. Motion passed unanimously.

5. Proposed for Notice of Intended Action to amend Chapter 21, "Electronic Data and Automated Systems in Pharmacy Practice," relating to electronic transmission petitions for exemption

Motion by Gayle Mayer, second by Erik Maki, to file for Notice of Intended Action. Motion passed unanimously.

6. Proposed for Notice of Intended Action to amend Chapter 6, "General Pharmacy Practice," Chapter 8, "Universal Practice Standards," and Chapter 10, "Controlled Substances," to require minimum security and monitoring system requirements, allow the dispensing of a prescription which requires counseling while the pharmacist is on a break if certain conditions are met, require all pharmacies to maintain a perpetual inventory log of all controlled substances, and require an exact count of all controlled substances for a controlled substances inventory count

Motion by Kathy Stone, second by Gayle Mayer, to file for Notice of Intended Action. Motion passed unanimously.

7. Proposed for Notice of Intended Action to amend Chapter 8, "Universal Practice Standards," to provide for notification to the board of the designation of an interim pharmacist in charge during an extended absence of the permanent pharmacist in charge

Motion by Gayle Mayer, second by Sherill Whisenand, to file for Notice of Intended Action. Motion passed unanimously.

8. Discussion of draft rules relating to Collaborative Practice Agreements

The draft rules will be forwarded to stakeholders for comment.

9. Discussion of draft NEW statewide protocols
 - d. Influenza test and treat
 - e. Strep A test and treat

The draft provided by IPA has been sent to Dr. Pedati for review.

10. DEA Final Rule relating to registration of Narcotic Treatment Programs w/Mobile Components - Information only

Informational Item.

Closed Session

At 10:51 a.m., on a motion by Gayle Mayer, second by Kathy Stone, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code section 21.5(1)(a), to review or discuss records which are required or authorized by state or federal law to be kept confidential; pursuant to Iowa Code

section 21.5(1)(d), to discuss whether to initiate licensee disciplinary investigations or proceedings; and pursuant to Iowa Code section 21.5(1)(f), to discuss the decision to be rendered in a contested case conducted according to the provisions of Iowa Code chapter 17A.

At 2:10 p.m., the Board returned to open session. In open session the following actions were taken:

1. Closed Session Minutes

Motion by Gayle Mayer, second by Joan Skogstrom, to approve the closed session minutes from the May 12, 2021 meeting as presented.

2. Notice of Hearing and Statement of Charges

Motion by Gayle Mayer, second by Sherill Whisenand, to approve the Notice of Hearing and Statement of Charges. Motion passed unanimously.

- A. 2020-0142 Medical Home Pharmacy, NRP License 4909, Trenton, NJ
- B. 2020-0102 Danielle Naughton, CPhT Registration 4083, DeWitt

3. Combined Statement of Charges, Settlement Agreement, and Final Order

Motion by Gayle Mayer, second by Sherill Whisenand, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in the following cases. Motion passed unanimously.

- A. 2020-0133 Manly Drug Store, License 834, Grundy Center
- B. 2020-0133 & 2021-0012 David Stefl, License 15768, Grundy Center
- C. 2021-0093 John Jensen, RPh, License 15650, Cedar Falls
- D. 2020-0143 Nathan Duke, RPh, License 18434, Cave Creek, AZ
- E. 2021-0020 Redlers LTC Pharmacy, License 3705, Omaha, NE

4. Combined Statement of Charges, Settlement Agreement, and Final Order

Motion by Gayle Mayer, second by Sherill Whisenand, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in the following cases. Jim Mennen recused. Motion passed unanimously.

- A. 2021-0037 Towncrest Pharmacy, License 838, Iowa City
- B. 2021-0039 Michael Deninger, License 17620, Iowa City
- C. 2021-0058 Mary Powers, CPhT Registration 3531

5. Closed with No Further Action

Motion by Gayle Mayer, second by Sherill Whisenand, to close with no further action the following investigative files in complaint numbers: 2021-0099, 2021-0019, 2021-0074, 2021-0073, 2021-0018, 2021-0116, 2021-0120, 2021-0121, 2021-0034, 2021-0086, 2021-0052, and 2021-0113. Motion passed unanimously.

6. Closed with No Further Action

Motion by Gayle Mayer, second by Sherill Whisenand, to close with no further action the following investigative files in complaint numbers: 2021-0059, 2020-0169, and 2021-0103. Jim Mennen recused. Motion passed unanimously.

7. Administrative Warning

Motion by Gayle Mayer, second by Sherill Whisenand, to issue Administrative Warnings to the respondents in the following investigative files in complaint numbers: 2021-0091, 2021-0079, 2021-0031, 2021-0032, 2021-0036, and 2021-0106. Motion passed unanimously.

8. Administrative Warning

Motion by Gayle Mayer, second by Sherill Whisenand, to issue Administrative Warnings to the respondents in the following investigative files in complaint numbers: 2021-0117 and 2021-0067. Jim Mennen recused. Motion passed unanimously.


9. Letter of Education

Motion by Gayle Mayer, second by Sherill Whisenand, to issue letters of education to the respondents in the following investigative files in complaint numbers: 2021-0066, 2021-0104, 2021-0105, 2021-0110, 2021-0111, 2021-0062, 2021-0082, 2021-0097, 2021-0089, and 2021-0098. Motion passed unanimously.

10. Letter of Education

Motion by Gayle Mayer, second by Sherill Whisenand, to issue letters of education to the respondents in the following investigative files in complaint numbers: 2021-0071 and 2021-0072. Jim Mennen recused. Motion passed unanimously.

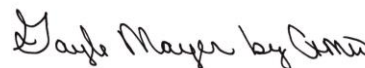
At 2:19 p.m., motion by Joan Skogstrom, second by Gayle Mayer, to adjourn. Motion approved unanimously.



Amanda Woltz, Administrative Assistant and Recording Secretary



Andrew Funk
Executive Director



Gayle Mayer
Board Vice-Chair