



Iowa Board of Pharmacy

May 3, 2022 Minutes

Members Present

Kathy Stone, Chair
Gayle Mayer, Vice-Chair
Bob Egeland
Erik Maki
Jim Mennen
Dane Nealson
Joan Skogstrom
Sherill Whisenand

Melissa Carstens, PMP Associate Administrator
Amanda Woltz, Administrative Assistant
Emily Albers, Pharmacist-Intern
Bella Blankenship, Pharmacist-Intern

Compliance Officers

Christie Carlson
Curt Gerhold
Mark Mather
Sue Mears
Jean Rhodes
Maggie Phelps
Jennifer Tiffany
Jim Wolfe

Staff Present

Andrew Funk, Executive Director
Laura Steffensmeier, Assistant Attorney General
Therese Witkowski, Executive Officer
Mitchell Barnett, Associate Director of PMP

Call to Order

At 9:00 a.m., on Tuesday, May 3, 2022, Kathy Stone, called the meeting of the Iowa Board of Pharmacy to order. Dane Nealson and Sherill Whisenand were absent when the meeting was called to order.

Closed Session

At 9:01 a.m., on a motion by Gayle Mayer, second by Joan Skogstrom, 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.

Dane Nealson joined the meeting at 9:02 a.m. and Sherill Whisenand joined the meeting at 9:08 a.m.

At 12:28 p.m., the Board returned to open session. Joan Skogstrom departed the meeting. The Board took a brief recess until 1:00 p.m.

Open session at 1pm – Kathy Stone called the open session of the meeting to order. Joan Skogstrom was absent with all other members present.

Public Comment Period

Iris Fung attended the public session to ask questions of the Board regarding prioritizing public complaints. Iris suggested to add a warning to the complaint form that a pharmacy personnel's words can be used against them. Andrew Funk suggested he would follow-up with Iris after the Board Meeting.

Approval of Minutes

1. March 1, 2022 Open Session Minutes

Motion by Dane Neilson, second by Sherill Whisenand, to approve the open session minutes of the March 1, 2022 meeting as presented. Motion passed unanimously.

NABP Verify – Bill Cover, RPh, Associate Executive Director, NABP State Pharmacy Affairs

Bill presented the NABP Verify Presentation.

AlixaRx's Innovative Pharmacy Pilot Project Quarterly Report

Amanda Stewart, Vice President of Pharmacy Support Services with AlixaRx provided a report on the pilot project. The pilot authorizes AlixaRx to install and operate AMDS technology in a select group of long term care facilities. This report includes January-March of this year.

Requests

1. Request to continue to waive 657 IAC 20.3 requiring compliance with USP 800 hazardous drug nonsterile compounding standards - University of Iowa Healthcare - Iowa River Landing Pharmacy, Pharmacy licenses 1419 and 1584, Iowa City

Angela Hunter was present and spoke to this request. Motion by Dane Neilson, second by Sherill Whisenand, to approve the request as presented. Motion passed unanimously.

2. Request to waive 657 IAC 8.35(6)"c" requiring that a change in pharmacy ownership occurs when the majority ownership interest of the owner changes - Cornerstone Apothecary, Pharmacy licenses 1329, 1354, and 1422, Van Horn, Marengo, and Belle Plaine

No one was present from Cornerstone Apothecary. Andrew Funk spoke to this request. Motion by Gayle Mayer, second by Jim Mennen, to approve as presented. Motion passed unanimously.

3. Request, pursuant to 657 IAC 8.35(6), to disassociate from prior discipline associated with a pharmacy license following an ownership change - NuCara #44, pharmacy license applicant, Grundy Center

Steve Martins was present to speak to the request. Dane Neilson recused. Motion by Gayle Mayer, second by Sherill Whisenand, to approve the request as presented. Motion passed unanimously.

4. Request to waive 657 IAC 21.10(3)"b" requiring pharmacist final verification on prescriptions filled utilizing an automated medication dispensing system - Hy-Vee Pharmacy Central Fill, Pharmacy license 5493, Omaha, NE

Jonathan Fransen and Cody Maxwell were present to speak to the request. Jim Mennen recused. Motion by Gayle Mayer, second by Dane Neilson, to approve the request as presented. Motion passed unanimously.

Reports & Informational Items

1. Executive Director's Report

Staffing

- Amanda Woltz has accepted a position with the Department of Natural Resources. She has been with the Board for the last 5 years. We thank Amanda for her dedication to the Board.
- Laura Steffensmeier – 9 years serving in the AAG role for the Board of Pharmacy
- Dakota Waltz and Deb McClure – 1 year as licensing specialists for the Board of Pharmacy

Licensing Update

- Pharmacist renewals opened May 1st and will continue without penalty until June 30th. Pharmacist CE must be reported to the NABP CPE monitor. Renewals will be audited by licensing staff. There are 3,302 pharmacists to renew this year and 49 have renewed online thus far.
- 3PLs renewal period closed on March 31st. Of the 137 licensed, four facilities allowed their license to expire and did not renew.

2. Meetings and Travel

- NABP Annual Meeting, Phoenix, AZ May 19-21, 2022
- IPA Pharmacy Expo May 17-18, 2022
- ASHP Summer Meeting, Phoenix, AZ June 11-15, 2022
- IPA’s Independent Community Practice Forum, Virtual June 21, 2022
- Next Board Meeting June 28-29, 2022
- NABP District V, Custer State Park, SD August 3-5, 2022

3. Legal Update

Laura Steffensmeier provided an update regarding open cases. Judicial review pending for the Empower case.

4. Prescription Monitoring Program (PMP) Update

Mitch Barnett provided a program update.

PMP Integrations

- In state chain pharmacies 172
- In state independent pharmacies..... 24
- Nonresident pharmacies 109
- Clinics/physician offices within Iowa..... 243
- Clinics/physician offices outside of Iowa 272
- Iowa hospitals..... 57
- Hospitals outside of Iowa..... 76

Pharmacist Narcan® Dispensing Program

- From July 1, 2020 to March 31, 2022 the Pharmacist Narcan® Dispensing Program has had 2,805 fills with 2,708 unique patients.

Pharmacist Disposal Kit Dispensing Program

- From July 1, 2021 to March 31, 2022 the Pharmacist Disposal Kit Dispensing Program has had 8,245 fills for 7,114 unique patients.

5. Board-Sponsored Medication Disposal Update

Melissa Carstens provided a program update.

The Board-Sponsored Medication Disposal program has a total number of 518 units in Iowa and has destroyed 97,066lbs of medication, as of April 2022.

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

Becky Carlson provided a program update. The last meeting was March 9, 2022 and the next meeting is scheduled for June 1, 2022.

Total program participants: 21

7. Compliance Update

Christie Carlson provided a compliance update. From 3/1/2022-4/30/2022 compliance officers have completed the following:

- 62 retail pharmacy inspections
- 12 hospital pharmacy inspections
- 11 low/medium risk sterile compounding inspections
- 4 retail compounding pharmacy inspections
- 19 controlled substance act inspections-veterinarians
- 3 controlled substance act inspections-dentists
- 226 controlled substance act inventory verification
- 2 wholesale distributor inspection
- 1 3PL/limited distributor
- 28 investigations completed
- 8 compliance officer meetings
- Other tasks and meetings shared

8. APhA Pharmacist Well-Being Index: NABP District V Informational Item

Discussion and Vote on Memorandum of Understanding (MOU) between the Iowa Department of Public Health (IDPH) and the Iowa Board of Pharmacy (Board)

Laura Steffensmeier presented and discussed the amended MOU with the creation of the division director to be clear on the information that can be shared with them.

Motion by Gayle Mayer, second by Dane Neilson, to approve the amended MOU. Motion passed unanimously.

Review of Federal Proposed Regulations/Opportunity to Submit Comments

1. Opportunity for comment on proposed DEA regulation to revoke the exemption of all butalbital products - comment period open until May 12, 2022

Sue Mears presented. Board is supportive of submitting comments.

2. Opportunity for comment on potential modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) to require that mail-back envelopes be dispensed and education on safe disposal provided with opioid analgesics dispensed in an outpatient setting - comment period open until June 21, 2022

Sue Mears presented. Board is supportive to submit comments at the May Rules Committee meeting.

3. Opportunity for comment on proposed FDA regulation for National Standards for the licensure of wholesale drug distributors and third-party logistics providers - comment period open until June 6, 2022

Sue Mears presented and requested additional time to prepare comments and present to the Rules Committee in May.

Rules and Legislation

1. Legislative Update

Sue Mears provided an update with an update regarding the Governor signed the CS bill. The Rules Committee will look at implementing these rules. The Senate has not taken up the pharmacy practice bill yet.

2. Proposed for Adoption and Filing to amend Chapter 20, "Compounding Practices," to authorize the limited dispensing of an office stock compounded preparation by a veterinarian to the owner of an animal patient (ARC 6178C)

Motion by Dane Nealson, second by Jim Mennen, to adopt. Motion passed unanimously.

3. Proposed for Adoption and Filing to amend Chapter 6, "General Pharmacy Practice," Chapter 8, "Universal Practice Standards," and Chapter 10, "Controlled Substances," to provide minimum security and monitoring system requirements to be utilized by Iowa pharmacies to prevent and detect unauthorized access to prescription drugs and records, require an exact measure or count of all schedules of controlled substances for a controlled substance inventory count, require a program to be established to monitor and ensure controlled substance accountability, require development and execution of a corrective action plan following the report of theft or loss of controlled substances, and require a controlled substance inventory to be taken with each change in pharmacist in charge (ARC 6179C)

Motion by Dane Nealson, second by Sherill Whisenand, to adopt. Motion passed unanimously.

4. Proposed for Notice of Intended Action to amend Chapter 10, "Controlled Substances," to temporarily place seven substances into Schedule I and one substance into Schedule IV of the Iowa

controlled substances Act in response to similar scheduling action by the federal Drug Enforcement Administration

Motion by Sherill Whisenand, second by Dane Nealson, to notice. Motion passed unanimously.

5. Proposed for Notice of Intended Action to amend Chapter 20, "Compounding Practices," to require documentation of ingredient source, lot and expiration date and the steps involved in the compounding process for all nonsterile and sterile compounded preparations

Motion by Dane Nealson, second by Sherill Whisenand, to notice. Motion passed unanimously.

Sherill Whisenand departed the meeting.

Closed Session

At 2:52pm., on a motion by Dane Nealson, second by Gayle Mayer, the Board voted unanimously by all members present (Joan Skogstrom and Sherill Whisenand absent) 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 3:45 p.m., the Board returned to open session. In open session the following actions were taken:

1. March 1, 2022 Closed Session Minutes

Motion by Dane Nealson, second by Gayle Mayer, to approve the closed session minutes from the March 1, 2022 meeting as presented. Motion passed unanimously.

2. Administrative Warning

Motion by Dane Nealson, second by Bob Egeland, to issue Administrative Warnings to the respondents in the following investigative files in complaint numbers: 2021-0224. Motion passed unanimously. Jim Mennen recused

Motion by Dane Nealson, second by Bob Egeland, to issue Administrative Warnings to the respondents in the following investigative files in complaint numbers: IMP3 referral (no complaint number assigned yet), 2021-0274, 2022-0080, 2021-0240, 2022-0076, and 2021-0241. Motion passed unanimously.

3. Letter of Education

Motion by Dane Nealson, second by Bob Egeland, to issue letters of education to the respondents in the following investigative files in complaint numbers: 2022-0050, 2022-0070, 2021-0269, 2021-0270, 2021-0163, 2022-0055, and 2022-0062. Motion passed unanimously.

4. Closed with No Further Action

Motion by Gayle Mayer, second by Bob Egeland, to close with no further action the following investigative files in complaint numbers: 2022-0051. Dane Nealson recused. Motion passed unanimously.

Motion by Dane Nealson, second by Bob Egeland, to close with no further action the following investigative files in complaint numbers: 2022-0005, 2022-0081, 2022-0052, 2022-0054, 2022-0063, 2022-0071, 2022-0064, 2022-0069, 2022-0045, 2022-0074, 2021-0213, 2022-0020, 2021-0284, 2022-0015, 2022-0016, 2022-0065, 2021-0268, 2022-0009, 2022-0053, 2022-0018, 2022-0067, 2021-0237, and 2022-0044. Motion passed unanimously.

5. Closed with No Further Action and Referral to Another Licensing Board

Motion by Dane Nealson, second by Bob Egeland, to close with no further action and refer to another licensing board, the following investigative files in complaint numbers: 2022-0058 and 2022-0017. Motion passed unanimously.

6. Settlement Agreement and Final Order

Motion by Dane Nealson, second by Bob Egeland, to approve the Settlement Agreement and Final Order in the following cases. Motion passed unanimously.

- A. 2021-0035 Heather Oberg, CPhT, Registration 9678, McCook Lake, SD
- B. 2021-0112 Cheveux LLC, Nonresident pharmacy, License 5366, Phoenix, AZ

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

Motion by Dane Nealson, second by Bob Egeland, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in the following cases. Jim Mennen recused. Motion passed unanimously.

- A. 2022-0072 Heather Gleason, CPhT, Registration 22784

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

Motion by Dane Nealson, second by Bob Egeland, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in the following cases. Motion passed unanimously.

- A. 2021-0261 Optum Infusion Services 501, Inc. Nonresident Pharmacy, License 5437, Las Vegas, NV

9. Notice of Hearing and Statement of Charges

- A. 2020-0175, 2020-0176, 2020-0177, 2020-0178, 2020-0179, 2020-0180, 2020-0181
 - a. (Walgreens 07967, License 1257, Clive, Walgreens 05060, License 1086, Clive, Walgreens 07454, License 197, Ankeny, Walgreens 359, License 778, Des Moines, and Walgreens 04714, License 459, Des Moines
 - b. 2020-0178 Walgreens 05721, License 355, Des Moines and 2020-0180 Walgreens 07455, License 1210, Waterloo
- B. 2021-0236
- C. 2021-0190 and 2022-0010

At 3:45pm, motion by Gayle Mayer, second by Dane Neilson, to return to open session, Motion approved unanimously.

At 3:55p.m., motion by Dane Neilson, second by Gayle Mayer, to adjourn. Motion approved unanimously.



Becky Carlson, IMP3 Case Manager and Interim Recording Secretary



Andrew Funk
Executive Director



Kathy Stone
Board Chair

APPROVED THIS 28th DAY OF JUNE 2022