



Iowa Board of Pharmacy

January 10, 2023 Minutes

Members Present

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

Compliance Officers

Curt Gerhold
Mark Mather
Sue Mears
Britney Origer
Maggie Phelps
Jean Rhodes
Jim Wolfe

Staff Present

Andrew Funk, Executive Director
Laura Steffensmeier, Assistant Attorney General
Mitchell Barnett, Associate Director of PMP
Becky Carlson, Administrative Assistant
Melissa Carstens, PMP Associate Administrator
Amanda Woltz, Administrative Assistant

Call to Order

At 9:07 a.m., on Tuesday, January 10, 2023, Kathy Stone, called the meeting of the Iowa Board of Pharmacy to order.

Public Comment Period

None

Approval of Minutes

1. October 25, 2022 Open Session Minutes

Motion by Dane Nealson, second by Sherill Whisenand, to approve the open session minutes of the October 25, 2022, meeting as presented. Motion passed unanimously.

Requests

1. Request to waive 657 IAC 21.10(3)"b" requiring pharmacist final verification on prescriptions filled utilizing an automated medication dispensing system
 - a. Hy-Vee Pharmacy Fulfillment Center, License 5538, Davenport

Motion by Dane Nealson, second by Erik Maki, to approve the request as submitted. Motion passed unanimously.

- b. Walmart Central Fill #10-2670, Application Pending, Spring, TX

Motion by Dane Nealson, second by Sherill Whisenand, to approve the request as submitted. Motion passed unanimously.

- 2. Request to waive 657 IAC 2.4(2) requiring a candidate for licensure by examination to pass all components in Iowa within a period of one year beginning with the date the candidate passed an initial component – Joshua Kim, Pharmacist-intern (expired) registration 6931, Des Moines

Motion by Erik Maki, second by Joan Skogstrom to approve the request through March 31, 2023. Motion passed unanimously.

Alixarx’s Innovative Pharmacy Pilot Project Quarterly Report

Amanda Stewart was present and reported on the new quarterly report. The report covers October - December 2022. They have seen a 4% increase in new admissions. AlixaRx dispensed 270,011 doses from the AMDS technology and 103,509 doses in traditional punch cards, for a total of 373,520 doses dispensed during the Q4 report period. 72% of the total medication needs for the facilities is being provided by the on-site AMDS technology while 28% is provided in punch card or bulk commercial packaging from the main dispensing pharmacy. These facilities continue to report significant a waste reduction vs a traditional punch card model with the AMDS model and the one-day supply daily dispensing. Final data will be presented in February 2023.

Reports & Informational Items

- 1. Executive Director’s Report Andrew Funk

Staffing

- The Board has hired Susan Wennekamp as the new licensing specialist responsible for wholesale distributors, limited distributors, 3PLs, and outsourcing facilities.
- Interviews for the open compliance officer position will be held this week.

Staff Anniversaries

- Executive officer, Terry Witkowski, is celebrating 37 years of service with the state of Iowa.
- Compliance officer, Curt Gerhold, is celebrating 11 years of service with the Board.
- Compliance officer, Sue Mears, is celebrating 10 years of service with the Board.

Nominations, Appointments, Presentations

- Board staff were invited to present at the IPA Resident Forum: “Board of Pharmacy, Friend not Foe” which will be held January 20, 2023.
- Board staff will present at the University of Iowa Pharmacy Law and Ethics class on February 13, 2023.
- Board members, Gayle Mayer, Sherill Whisenand, and Bob Egeland, have terms that are up for reappointment in 2023.

USP Revisions

- Compliance officer, Britney Origer will provide a high-level overview of the updates made to USP 795/797. Board staff plan to work with an Iowa-based continuing education provider to put together a 1–2-hour live webinar with on-demand capabilities to highlight these changes. This ACPE accredited continuing education will be available at no cost to licensees.
- Correction – at the October 2022 meeting it was incorrectly stated that the USP revisions would be effective June 1, 2023. However, after further research and confirmation, the effective date for the revisions is November 1, 2023.

Licensing (Current Licenses/Registrations Only)

Licensing data as of January 1, 2023 compared to January 1, 2022

- Pharmacists: 6,540 (2% decrease)
- Interns: 915 (6.4% decrease)
- Technicians: 5044 (21.6% decrease)
- Tech Trainees: 1662 (29.6% decrease)
- PSPs: 3440 (14.5% increase)
- CSAIs 20062 (4.3% increase)
- CSABs 2904 (1% increase)
- Pharmacy In state 851 (5% decrease)
- Pharmacy NR 865 (2% decrease)
- Wholesaler 350 (6% decrease)
- Limited Distributor 1285 (3% decrease)
- 3PL 148 (6.5% increase)
- Outsourcing Facility 43 (7.5% increase) (note:77 currently registered with FDA nationwide)

2. Meetings and Travel Andrew Funk

- Pharmacy Stakeholders Meeting – Drake University.....January 24, 2023
- Pharmacist Day on the HillJanuary 25, 2023
- PharmaCE ExpoFebruary 3-5, 2023
- Rules CommitteeFebruary 4, 2023
- Drake Health Professions DayFebruary 24, 2023
- Next Board meeting.....February 28, 2023

3. Legal Update.....Laura Steffensmeier

Laura Steffensmeier provided an update regarding open cases. The Empower Pharmacy appeal is scheduled for oral argument for Wednesday, January 11, 2023. The Board may have a resolution by the February or May Board meeting.

4. Prescription Monitoring Program (PMP) UpdateMitch Barnett

Mitch Barnett provided a program update.

PMP Integrations

- In state chain pharmacies 307
- In state independent pharmacies..... 57

- Nonresident pharmacies 139
- Clinics/physician offices within Iowa 292
- Clinics/physician offices outside of Iowa..... 339
- Iowa hospitals..... 71
- Hospitals outside of Iowa 90

Statewide Integration Initiative

- The Statewide Integration Initiative launched June 15, 2022. The initiative provides funding for a statewide PMP integration option that is available to Iowa prescribers and pharmacists. 121 new entities have signed up since it launched. Addition information concerning the Statewide Integration Initiative can be found at <https://pharmacy.iowa.gov/prescription-monitoring-program>.

Quarterly Prescriber Activity Reports

- 11,338 reports were sent this quarter.

Pharmacist Narcan® Dispensing Program

- From July 1, 2020 to December 30, 2022 the Pharmacist Narcan® Dispensing Program has had 5,163 fills with 4,800 unique patients.

Pharmacist Disposal Kit Dispensing Program

- From July 1, 2021 to December 30, 2022 the Pharmacist Disposal Kit Dispensing Program has had 22,000+ fills for 16,000+ unique patients.

PMP Meetings and Presentations

- Iowa Hospital Association.....January 25, 2023
- Public Health Conference of IowaMarch 28, 2023

5. Board-Sponsored Medication Disposal Update Melissa Carstens

Melissa Carstens provided a program update. The program has over 520 participating pharmacies (both controlled and non-controlled sites). Pharmacies are able to install an 18 gallon or 38 gallon DEA-compliant permanent receptacle.

In December, the program serviced 316 twenty-two gallon, 57 twenty gallon, 3 eighteen gallon, and 1 thirty-eight-gallon liners.

The program destroyed 15424.77 lbs. of pharmaceutical waste which is 8886 lbs. more than the last quarterly total. This increased trend shows that the program remains to get rid of pharmaceutical waste in a safe, responsible manner.

6. Iowa Monitoring Program for Pharmacy Professionals (IMP3) UpdateBecky Carlson

Becky Carlson provided a program update. The last meeting was December 7, 2022, and the next meeting is scheduled for March 8, 2023.

Total program participants: 18

7. Compliance Report Maggie Phelps

Maggie Phelps provided a compliance update. Since November 1, 2022, some of the items that compliance officers have been working on are COVID-19 Test to Treat Protocol, lecture to Drake P1 students on intern responsibilities, compliance monitoring of licensee probation conditions, Board presentation on UPS 795 and 797 revision updates, development of CEU presentation for USP 795 and 797 revision updates, audit of EMS programs for CSA registration, and implementation of the Esper rulemaking platform.

Compliance officers have attended the 2022 FDA 2022 Virtual Intergovernmental Working Meeting, USP Virtual Forum on 795/797 Changes, NABP webinars, ASHP Midyear, NASCSA Education webinars, and QI Council meetings.

- Inspections completed from November 1, 2022 to December 31, 2022 total 84.
- Controlled Substance Act inventory verification for inspection total 146.
- Controlled Substance Act inspections total 10.

8. Updates to USP General Chapters <795> and <797>Britney Origer

Britney Origer presented her report on the updates to USP General Chapters <795> and <797>. The revisions are to provide minimum compounding standards, not best practices. The revisions will become official November 1, 2023.

9. Well-being Index for Pharmacy Personnel Report

Informational Item

Rules and Legislation

1. Iowa Pharmacy Association (IPA) 2023 Legislative Priorities

Seth Brown presented IPA’s legislative priorities, ensuring compliance with last year’s PBM bill through the regulatory process, modernizing the Iowa pharmacy practice act, and securing continued funding for Medicaid pharmacy reimbursement.

No motion by the Board.

2. Vote to Delegate Lobbying Authority to Executive Director

Motion by Sherill Whisenand, second by Dane Neelson, to delegate authority to the Executive Director to speak on behalf of the Board for the legislative session. Motion passed unanimously

3. Proposed for adoption to amend Chapter 10, “Controlled Substances,” to temporarily place one substance into Schedule I of the Iowa Controlled Substances Act in response to similar action taken by the federal Drug Enforcement Administration (ARC 6532C)

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

4. Proposed for adoption to amend Chapter 37, "Iowa Prescription Monitoring Program," establishing council membership information and to clarify that only overdose-reversal opioid antagonists are required to be reported to the PMP (ARC 6533C)

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

5. Proposed for notice of intended action to amend Chapter 10, "Controlled Substances," to temporarily place four substances into Schedule I, exclude one substance from Schedule II, and add one substance as a precursor substance to the Iowa Controlled Substances Act in response to similar action taken by the federal Drug Enforcement Administration

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

6. Proposed for notice of intended action to amend Chapter 33, "Military Service and Veteran Reciprocity," to add active duty military spouse to the expedited processing of applications for license transfer and issuance of a temporary license when appropriate (2022 Iowa Acts, Senate File 2383)

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

7. Proposed for notice of intended action to amend Chapter 10, "Controlled Substances," Chapter 21, "Electronic Data and Automated Systems in Pharmacy Practice," and Chapter 23, "Care Facility Pharmacy Practice," to authorize the installation and operation of automated medication distribution systems (AMDS) by pharmacies in care facility settings

No motion – referred back to Rules Committee for further review.

8. Proposed for notice of intended action to amend Chapter 10, "Controlled Substances," to authorize the issuance, on a case-by-case basis, a registration to a business location when it would be impractical to require each individual practitioner who administers or dispenses controlled substances to separately register at the business location, such as ambulatory surgical centers, dialysis centers, federally qualified health centers, and standalone clinics associated with a hospital system

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

IMP3 Committee Member Application Review

Erik Maki recused himself at 11:24 a.m.

At the December 7, 2022 meeting the IMP3 committee reviewed seven applications for new IMP3 committee members and have referred four applicants to the Board for review for appointment. The committee has requested that the Board appoint two of the four applicants to the committee.

Motion by Sherill, second by Dane Nealson, to appoint pharmacist John Vallandingham and pharmacist Sarah Grady to the IMP3 committee. Motion passed unanimously with Erik Maki abstaining.

Erik Maki returned at 11:32 a.m.

Closed Session

At 11:34 a.m., on a motion by Dane Nealson, second by Jim Mennen, 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 4:22 p.m., the Board returned to open session. In open session the following actions were taken:

1. October 25, 2022 Closed Session Minutes

Motion by Dane Nealson, second by Sherill Whisenand, to approve the closed session minutes from the October 25, 2022 meeting as presented. Motion passed unanimously.

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

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

- A. 2022-0162 Michael Bierie, DDS, CSA 1418276, Dubuque
- B. 2021-0255 & 2022-0095 CVS Pharmacy #10329, License 1506, Des Moines
- C. 2022-0130 Natasha Konfrst, RPh, License 24342, Urbandale

3. Settlement Agreement and Final Order

Motion by Sherill Whisenand, second by Gayle Mayer, to approve the Settlement Agreement and Final Order in the following case. Motion passed unanimously.

- A. 2021-0083 Mint Pharmacy & Skin Clinic, NRP License 4635, North Palm Beach, FL

4. Closed with No Further Action

Motion by Dane Nealson, second by Sherill Whisenand, to close with no further action the following investigative files in complaint numbers: 2021-0063, 2021-0064, 2020-0072, 2022-0202, 2022-0168, 2022-0175, 2022-0233, 2022-0181, 2022-0236, 2021-0090, 2022-0100, 2022-0101, 2022-0173, 2022-0198, 2022-0110, 2022-0165, 2022-0124, 2022-0125, 2022-0183, 2022-0176, 2022-0169, 2022-0191, 2022-0196, 2022-0212, 2022-0190, 2022-0201, 2022-0194, 2022-0218, 2022-0228, 2022-0174, 2022-0189, 2022-0225, 2022-0226, 2022-0197, 2022-0207, 2022-0208, and 2022-0195. Motion passed unanimously.

5. Closed with No Further Action

Motion by Dane Neelson, second by Sherill Whisenand, to close with no further action the following investigative files in complaint numbers: 2022-0214, 2022-0215, 2022-0193, 2022-0213. Jim Mennen abstained. Motion passed unanimously.

6. Administrative Warning

Motion by Dane Neelson, second by Sherill Whisenand, to issue administrative warnings to the respondents in the following investigative files in complaint numbers: 2022-0060, 2022-0135, 2022-0123, 2022-0223, and 2022-0203. Motion passed unanimously.

7. Administrative Warning

Motion by Dane Neelson, second by Sherill Whisenand, to issue administrative warnings to the respondents in the following investigative files in complaint numbers: 2022-0172, 2022-0188, 2022-0220, 2022-0221, and 2022-0222. Jim Mennen abstained. Motion passed unanimously.

8. Administrative Warning

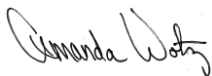
Motion by Sherill Whisenand, second by Gayle Mayer, to issue administrative warnings to the respondents in the following investigative files in complaint numbers: 2022-0187, 2022-0211, 2022-0114, 2022-0227, 2022-0237, and 2022-0250. Dane Neelson abstained. Motion passed unanimously.

9. Letter of Education

Motion by Dane Neelson, second by Sherill Whisenand, to issue letters of education to the respondents in the following investigative files in complaint number: 2022-0180, 2022-02301, and 2022-0199. Motion passed unanimously.

10. Motion by Dane Neelson, second by Sherill Whisenand, to correct the prior vote approving Administrative Warnings in cases 2022-0187 and 2022-0211 and instead approving Letters of Education. Motion passed unanimously.

At 4:30 p.m., motion by Dane Neelson, second by Gayle Mayer, to adjourn. Motion approved unanimously.



Amanda Woltz, Administrative Assistant and Recording Secretary



Andrew Funk
Executive Director



Kathy Stone
Board Chair

APPROVED THIS DAY OF FEBRUARY 28, 2023