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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

F I N A L M I N U T E S

MEETING OF:

STATE BOARD OF PHARMACY

TIME: 10:32 A.M.

Held at

PENNSYLVANIA DEPARTMENT OF STATE

2525 North 7th Street

CoPA HUB, Eaton Conference Room

Harrisburg, Pennsylvania 17110

as well as

VIA MICROSOFT TEAMS

January 21, 2025

State Board of Pharmacy
January 21, 2025

BOARD MEMBERS:

Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson
Arion R. Claggett, Acting Commissioner, Bureau of
Professional and Occupational Affairs
Eric Esterbrook, R.Ph., Vice Chairperson
Janet Getzey Hart, R.Ph., Secretary
John R. Slagle, R.Ph.
Tyler W. Ritchie, Esquire, Deputy Attorney General,
Office of Attorney General
James Reed Jr., R.Ph.

BUREAU PERSONNEL:

Sean C. Barrett, Esquire, Board Counsel
Ray J. Michalowski, Esquire, Senior Board Prosecutor
Nathan C. Giunta, Esquire, Board Prosecution Liaison
Caroline A. Bailey, Esquire, Board Prosecutor
Tyesha C. Miley, Esquire, Board Prosecutor
Ashley P. Murphy, Esquire, Board Prosecutor
Sara Trimmer, Pharm.D., R.Ph., Executive Secretary
Thomas Leech, Board Administrator
Marc Farrell, Esquire, Regulatory Counsel,
Office of Chief Counsel, Department of State
Andrew LaFratte, MPA, Deputy Policy Director,
Department of State
Carlton Smith, Esquire, Deputy Chief Counsel,
Prosecution Division
Cathy A. Tully, Esquire, Board Counsel, State Board
of Massage Therapy
Michael P. Merten, Esquire, Board Counsel, State
Board of Barber Examiners
Elle Thompson, Law Clerk, PA Department of State

ALSO PRESENT:

Theresa M. Talbott, R.Ph., Director, Pharmacy and
Retail Advocacy, CVS Pharmacy
Larry Jones, Pennsylvania Society of Health-System
Pharmacists
Rhonda Thomas, PharmD, MBA, BSPS, BCSCP, Director of
Pharmacy, Lehigh Valley Health Network

State Board of Pharmacy
January 21, 2025

ALSO PRESENT: (cont.)

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7 Grace Sesi, Executive Director, Regulatory Affairs at
8 CVS Health/Chairperson, Michigan Board of Pharmacy
9 Anthony Bixler, WellSpan York Hospital/Pennsylvania
10 Society of Health-System Pharmacists
11 Daniel Longyhore, System Director, Knowledge
12 Management for Pharmacy at Geisinger
13 Jill Rebuck, PharmD, MBA, FCCM, FCCP Executive
14 Director Pennsylvania Society of Health-System
15 Pharmacists
16 Natalie Klek, PharmD, TTS, Executive Fellow, Student
17 - Pennsylvania Pharmacists Association
18 Katelyn Mulcan, Foundation Director, Student
19 Pennsylvania Pharmacists Association
20 Kim Wilkin, Advocate, Pennsylvania Pharmacists
21 Association
22 Jordan Childress, PGY1 Pharmacy Resident, WellSpan
23 York Hospital
24 Kerry Maloney, Esquire, Associate Counsel, University
25 of Pittsburgh Medical Center
26 Austin Agren, PharmD, WellSpan York Hospital
27 Nicole Fidler, Associate, Malady & Wooten
28 Katie Medei, Walgreens Pharmacy
29 Misha Patel, M.D., Curriculum Education Assistant,
30 Geisinger Commonwealth School of Medicine
31 Christina Antoun Pharmacy Licensing, Research, and
32 Regulatory Affairs, REAL Solutions Group LLC
33 Christopher Miller, Pharm.D., Giant Eagle
34 Tiffany Booher, MA, LPC, CAADC, CIP, CCSM, Director,
35 Peer Assistance Monitoring Programs; Program
36 Director, Physicians' Health Program, Pennsylvania
37 Medical Society
38 Victoria Elliott, RPh, MBA, CAE, Chief Executive
39 Officer, Pennsylvania Pharmacists Association
40 Nicole Sidle, Republican Executive Director, House
41 Professional Licensure Committee
42 David Klinger, RPh, Director of Pharmacy, Geisinger
43 Medical Center
44 Joseph Milward, Senior Manager, Pharmacy Quality and
45 Accreditation, PANTHERx Rare Pharmacy
46 Deena Parmelee, Legal Office Administrator 1,
47 Department of State
48 Arpit Mehta, Pharm.D., MPH, Director of Pharmacy,
49 Allegheny General Hospital, Pennsylvania Society of
50 Health-System Pharmacists

State Board of Pharmacy
January 21, 2025

ALSO PRESENT: (cont.)

William Lebak II, PharmD, Walgreens Boots Alliance
Susan DelMonico, R.Ph., JD
Steven L. Sheaffer, PharmD, FASHP, Pennsylvania
Society of Health-System Pharmacists
Wesley J. Rish, Esquire, Rish Law Office, LLC
Judy Kutchman, R.Ph., AllianceRx Walgreens Prime
Edward Foote, Pharm.D., FCCP, BCPS, Dean,
Philadelphia College of Pharmacy at the University
of Sciences
Jonathan Ference, Pharm.D., Dean, Wilkes University
Nesbitt School of Pharmacy
Dawn Cardamone, Express Scripts
Michelle Aytay, Manager, Pharmacy Affairs, Walgreens
Steven Zahn, Pharmacy Inspector, Bureau of
Enforcement and Investigation, Department of State
Valerie Pentland, PharmD, ConnectiveRx
Rebecca Taylor, Pharm.D., Vice President, Pharmacy
Services, University of Pittsburgh Medical Center
Regan Ceraso, RPh, BPharm, Quality Director, Medical
- Health Professions Program, Carnegie Mellon
University
Brittany Venturella, PharmD, Manager of Clinical,
Specialty and Central Fill Pharmacy Services at
Weis Markets
Jacquelyn Sassaman, Pentec Health
Joseph Salandra
Lisa Scannapieco, Vice President, Corporate and
Regulatory Compliance, Pentec Health
James Maister
Matthew Schwarztrauber, Pharmacy Technician, Veterans
Affairs Medical Center
Janis Levit, Divisional Pharmacy Manager, New
Albertsons, Inc.
Matthew Schonder, RPh, MBA, Director of Pharmacy,
University of Pittsburgh Medical Center McKeesport
Madeline Stauffer, PharmD, Lehigh Valley Health
Network
JP Burkhart
Margaret Barcam Senior Manager, Pharmacy Technical,
University of Pittsburgh Medical Center
Jennifer Hall
Nhi Lo, Pharmacy Intern, Wegmans Food Markets

State Board of Pharmacy
January 21, 2025

ALSO PRESENT: (cont.)

Kate McCale, Vice President, Compliance & Regulatory
Affairs, Hospital and Healthsystem Association of
Pennsylvania

Andrea Sargent, Director of Pharmacy, University of
Pittsburgh Medical Center Mercy

Vinay Arora, RPh, JD, Cardinal Health

Jermin Adrawy, Touro College of Pharmacy Student

Lauren Finoli, Manager of Pharmacy Clinical Services,
Allegheny General Hospital

Trisha Miller, PharmD, MPH, BCACP, Ambulatory Care &
Public Health Pharmacist, University of Pittsburgh
Medical Center

Richard Long

Christian Nobles, Alliance for Pharmacy Compounding

Amanda Abernathy, Director of Population Health and
Quality at UNC Health Blue Ridge

Sheetal Kamath, MPharm, RPh, University of Pittsburgh
Medical Center Presbyterian Shadyside

Katie Johnston, Community Pharmacy

Ben

Kimberly S. Wiesenbach

Hope Glembo, Legal Counsel, Empower Pharmacy

Jordan Brown, PharmD, Gayco Healthcare

Afnan Mohsin Pharmacy Intern, Vanderbilt University
Medical Center

Adam Womack Pharmacist In Charge, LifeMD

Colleen Kuzy

Andrew Frank Kuzy, R.Ph.

John

Allison Walker, Sargent's Court Reporting Service,
Inc.

1 ***

2 State Board of Pharmacy

3 January 21, 2025

4 ***

5 [Pursuant to Section 708(a)(5) of the Sunshine Act,
6 at 9:00 a.m., the Board entered into Executive
7 Session with Sean C. Barrett, Esquire, Board Counsel,
8 for the purpose of conducting quasi-judicial
9 deliberations and to receive the advice of Board
10 Counsel. The Board returned to open session at
11 10:30 a.m.]

12 ***

13 The regularly scheduled meeting of the State
14 Board of Pharmacy was held on Tuesday, January 21,
15 2025. Christine Roussel, Pharm.D., BCOP, BCSCP,
16 Chairperson, called the meeting to order at
17 10:32 a.m.

18 ***

19 Introduction of Board Members/Attendees
20 [Christine Roussel, Pharm.D., BCOP, BCSCP,
21 Chairperson, requested an introduction of Board
22 members and attendees.]

23 ***

24 [Sean C. Barrett, Esquire, Board Counsel, noted the
25 meeting was being recorded, and those who continued

1 to participate were giving their consent to be
2 recorded.

3 Mr. Barrett also noted the Board entered into
4 Executive Session for the purpose of conducting
5 quasi-judicial deliberations on a number of matters
6 that are currently pending before the Board and to
7 receive the advice of counsel.]

8 ***

9 Approval of the Minutes

10 CHAIR ROUSSEL:

11 Are there any edits or amendments to the
12 minutes for the December 7 meeting?

13 Hearing no edits.

14 Motion to approve the minutes?

15 MR. ESTERBROOK:

16 Motion to approve the minutes.

17 MS. GETZEY HART:

18 Second.

19 CHAIR ROUSSEL:

20 Any discussion? Let's call the roll.

21

22 Hart, aye; Reed, aye; Esterbrook, aye;

23 Claggett, aye; Ritchie, aye; Slagle, aye;

24 Roussel, aye.

25 [The motion carried unanimously.]

1 ***

2 Report of Board Prosecution - No Report

3 ***

4 Report of Board Counsel - Proposed Adjudication and
5 Order

6 CHAIR ROUSSEL:

7 Based on Executive Session deliberations
8 at item 4 on the agenda, I believe the
9 Board Chair would entertain a motion to
10 have counsel draft an Adjudication and
11 Order consistent with Executive Session
12 discussions at Case No. 20-54-011597,
13 Keesha Dinkins Jones, R.Ph.

14 MR. ESTERBROOK:

15 So moved.

16 MS. GETZEY HART:

17 Second.

18 CHAIR ROUSSEL:

19 Any discussion? Let's call the vote.

20
21 Hart, aye; Reed, aye; Esterbrook, aye;
22 Claggett, aye; Ritchie, aye; Slagle, aye;
23 Roussel, aye.

24 [The motion carried unanimously.]

25 ***

1 Report of Board Counsel - Final Adjudication and
2 Order

3 CHAIR ROUSSEL:

4 Item 5 on the agenda. Based on Executive
5 Session deliberations, I believe the
6 Board Chair would entertain a motion to
7 approve the Final Adjudication and Order
8 at Case No. 23-54-009558, Andrew Frank
9 Kuzy, R.Ph.

10 MR. ESTERBROOK:

11 So moved.

12 MS. GETZEY HART:

13 Second.

14 CHAIR ROUSSEL:

15 Any discussion? Hearing none. We'll
16 call the vote.

17

18 Hart, aye; Reed, aye; Esterbrook, aye;
19 Claggett, aye; Ritchie, aye; Slagle, aye;
20 Roussel, aye.

21 [The motion carried unanimously.]

22

23 Report of Board Counsel - Matter for Deliberation

24 CHAIR ROUSSEL:

25 Item 6 on the agenda. Based on Executive

1 Session deliberations, I believe the
2 Board Chair would direct counsel to draft
3 an Adjudication and Order consistent with
4 Executive Session deliberations at Case
5 No. 24-54-011733, James Josiah, R.Ph.

6 MR. ESTERBROOK:

7 So moved.

8 MS. GETZEY HART:

9 Second.

10 CHAIR ROUSSEL:

11 Any discussion? Call the vote.

12

13 Hart, aye; Reed, aye; Esterbrook, aye;
14 Claggett, aye; Ritchie, aye; Slagle, aye;
15 Roussel, aye.

16 [The motion carried unanimously.]

17

18 Review of Applications

19 CHAIR ROUSSEL:

20 Item 8 is James Maister. Based on
21 Executive Session deliberations, I
22 believe the Board Chair would entertain a
23 motion to deny the Request to Waive the
24 NAPLEX of this Applicant.

25 MR. ESTERBROOK:

1 So moved.

2 MS. GETZEY HART:

3 Second.

4 CHAIR ROUSSEL:

5 Any further discussion? We'll call the
6 vote.

7

8 Hart, aye; Reed, aye; Esterbrook, aye;
9 Claggett, aye; Ritchie, aye; Slagle, aye;
10 Roussel, aye.

11 [The motion carried unanimously.]

12

13 CHAIR ROUSSEL:

14 Item 9 is Jigneshkumar Bhagat. Based on
15 Executive Session deliberations, I
16 believe the Board Chair would entertain a
17 motion to approve the Applicant to take
18 the MPJE.

19 MR. ESTERBROOK:

20 So moved.

21 MS. GETZEY HART:

22 Second.

23 CHAIR ROUSSEL:

24 Any further discussion?

25

1 Hart, aye; Reed, aye; Esterbrook, aye;
2 Claggett, aye; Ritchie, aye; Slagle, aye;
3 Roussel, aye.

4 [The motion carried unanimously.]

5 ***

6 Appointment - Annual Prosecution Report

7 [Carlton Smith, Esquire, Deputy Chief Counsel,
8 Prosecution Division, presented the Annual
9 Prosecution Report for 2024. He reported over 46,000
10 active licensees for the State Board of Pharmacy. He
11 noted 738 cases were opened in 2024. 334 were
12 currently open, and 714 cases were closed. He
13 mentioned the average age to close a case was 195
14 days in 2024 and 271 days in 2023, noting their goal
15 to close a case is under 365 days.

16 Mr. Smith reported 23 fines, 28 citation fines
17 under Act 48, 19 probationary cases, and 12
18 suspensions in 2024.

19 Mr. Smith addressed cases where there was no
20 discipline under prosecution not-warranted cases and
21 reported 311 cases. He mentioned that prosecution
22 not-warranted is usually the largest number of closed
23 cases across all boards. He reported 25 instances
24 where there were no violations from the outset and 4
25 instances where there was no jurisdiction.

1 Mr. Smith reported 163 warning letters under Z18,
2 which are usually the second largest category of
3 cases closed without discipline. He explained that
4 prosecution looks at the strength of the case,
5 witnesses, documentation, expert opinions, and
6 disciplinary history to determine whether a warning
7 letter is appropriate.

8 Mr. Smith reported 48 complaints were withdrawn
9 under Z05 in 2024, which was slightly up by about 10
10 cases from 2023. He also reported 4 individuals
11 entered into the Voluntary Recovery Program and 9
12 completed in 2024.

13 Chair Roussel thanked Mr. Smith for working so
14 hard on their behalf and expediting the average time
15 to close the cases.

16 Ray J. Michalowski, Esquire, Senior Board
17 Prosecutor, informed Board members that many cases
18 are withdrawn because of counter cases, where a
19 conflict arises often caused by insurance, because an
20 individual was denied payment but withdraws it
21 afterwards.

22 Mr. Michalowski mentioned that more warning
23 letters were given in 2024 partly due to the
24 Pennsylvania Licensing System (PALS) issue with the
25 notification of the pharmacist-in-charge changes,

1 where the warning letters were stopped and letters of
2 concern were sent. He mentioned the Board is also
3 changing the number of days on that with their
4 regulation packages. He noted also seeing more
5 compliance with the updated USP Chapters 795, 797,
6 and 800.

7 Chair Roussel referred to USP 800 and the new
8 compounding regulations, noting they were effective
9 November 2023. She mentioned 2024 just passed,
10 noting there is probably a little bit heavier
11 inspection and asked whether prosecution had any
12 insight to share from the inspectors.

13 Mr. Michalowski explained that USP Chapter 800
14 has caused the most confusion in the industry. He
15 stated people were already anticipating Chapter 795
16 and Chapter 797 even with the changes and updates.

17 Mr. Giunta mentioned inspectors cannot give
18 advice but believed it is just a learning curve, and
19 inspectors are working with the pharmacies. He noted
20 inspectors sometimes bring situations to him and Mr.
21 Michalowski to decide how to handle the issues.

22 Chair Roussel referred to a discussion a couple
23 years ago concerning creating some type of ability to
24 do education, much like a VRP agreement, but with the
25 compounder specifically to keep their issues

1 confidential but mandate education instead of
2 discipline and more specific ones. She asked what
3 kind of training inspectors receive.

4 Mr. Michalowski explained that inspectors have
5 gone to conferences in the past but do not
6 essentially keep up to date because it is a separate
7 entity with the Bureau of Enforcement and
8 Investigation (BEI). He reported staff seem to be
9 very up to date and attend training nationally.

10 Mr. Michalowski mentioned that Chapter 800 is the
11 one with the most need as far as working with
12 inspectors because everything seems, especially with
13 automated dispensing machines or automated pill
14 counters, along with the standards for drugs that
15 would qualify under Chapter 800. He mentioned there
16 is a remedial program working in the background
17 because not every single failure is would result in a
18 legal case.

19 Chair Roussel asked how the Board of Pharmacy
20 rates with other boards as far as cases versus the
21 number of licensees.

22 Mr. Michalowski explained that it depends on the
23 profession, where some boards tend to be rule
24 followers, including the Board of Pharmacy. He
25 mentioned more complaints will be seen with boards

1 doing competitive sales and with consumer-related
2 boards.

3 Mr. Michalowski noted cases have been going up
4 over the last two years, and many of the cases that
5 are closers are cases where there is frustration due
6 to insurance denials and delays. He mentioned the
7 staff does great as a whole, and it will be
8 interesting when the techs are registered and
9 eligible for discipline.

10 Mr. Michalowski noted Ms. O'Malley discussed
11 updating their Act 48 Schedule, which is their
12 Schedule of Citations. He noted areas that could use
13 citations are nonresident pharmacy and compounding
14 regulations.

15 Chair Roussel referred to the regulatory work
16 session, noting the compounding section is the last
17 section in their regulatory package.

18 Mr. Michalowski mentioned that the best time to
19 talk about that is after the other two packages are
20 in the pipeline.]

21

22 Report of Board Counsel - Miscellaneous Items -

23 Sunshine Act and Recusal

24 [Sean C. Barrett, Esquire, Board Counsel, presented
25 an overview of the Pennsylvania Sunshine Act and

1 Recusal Guidelines.

2 Mr. Barrett explained the purpose of the Sunshine
3 Act is the right of the public to be present at all
4 meetings of agencies.

5 Mr. Barrett stated anytime an agency holds a
6 meeting, where deliberations or official actions take
7 place, the meeting must be open to the public after
8 public notice of the meeting. He noted an agency
9 includes the Board.

10 Mr. Barrett explained that deliberations are
11 discussions of agency business held for the purpose
12 of making a decision. He further explained that
13 official action includes decisions and votes taken on
14 motions, proposals, resolutions, rules, regulations,
15 ordinances, reports, or orders.

16 Mr. Barrett addressed public notice. He also
17 noted special meetings must be posted at least 24
18 hours in advance. He mentioned that public notice is
19 not required for emergency meetings or conferences.

20 Mr. Barrett explained that public notice includes
21 the place, date, and time of the meeting in a public
22 newspaper, principal office of the agency holding the
23 meeting, and on their website.

24 Mr. Barrett addressed the recording of votes,
25 where all votes must be publicly cast and recorded in

1 public session. He noted the requirements for
2 virtual presence at a meeting include being seen as
3 well as heard. He stated written minutes must be
4 kept of all meetings and made available to the
5 public.

6 Mr. Barrett noted the only exceptions for the
7 open meeting requirements are for conferences and
8 executive session. He mentioned that conferences are
9 basically training programs, where it is mostly
10 information for the Board. He noted deliberation of
11 agency business may not be discussed at a conference.

12 Mr. Barrett explained that executive session is
13 for discussing personnel issues and consulting with
14 attorneys regarding information concerning litigation
15 and to review agency business that would violate a
16 lawful privilege if conducted in public.

17 Mr. Barrett mentioned that items discussed in
18 executive session are quasi-judicial matters in terms
19 of disciplinary proceedings. He noted that official
20 action on matters discussed in executive session must
21 be taken at an open meeting.

22 Mr. Barrett addressed legal challenges for
23 violations of the Sunshine Act, noting challenges
24 must be filed within 30 days from the date of the
25 meeting or within 30 days from the discovery of any

1 action that occurred at a meeting. He stated no
2 action may be filed more than a year from the date of
3 the meeting in which a violation occurred.

4 Mr. Barrett addressed penalties for violations of
5 the Sunshine Act. He mentioned that a court may
6 declare all official actions taken at a meeting
7 invalid if there is a Sunshine Act violation. He
8 stated Board business should be conducted in open
9 meetings, and Board members should not discuss agency
10 business, especially matters discussed in executive
11 session, outside of the official Board meeting.

12 Mr. Barrett stated deliberations for committee
13 meetings also have to take place in an open meeting
14 with public notice, but committees that perform
15 administrative functions or probable cause screening
16 functions are not subject to open meeting
17 requirements.

18 Mr. Barrett addressed Recusal Guidelines, noting
19 recusal is mandatory when a Board member has a
20 prosecutorial role in the matter, including being a
21 member of the Probable Cause Screening Committee or
22 having a direct personal financial interest in the
23 outcome of the matter.

24 Mr. Barrett noted it is strongly suggested to
25 recuse if a Board member has a personal affection for

1 someone directly involved but simply knowing a person
2 or knowing of a person is not necessarily enough to
3 warrant recusal. He noted it is also strongly
4 suggested to recuse if they have knowledge from
5 outside of a case and cannot set it aside in order to
6 make a fair and unbiased determination.

7 Mr. Barrett addressed discretionary recusal,
8 where Board members should recuse themselves if the
9 member cannot make a decision on a subject fairly
10 without prejudice. He encouraged Board members to
11 contact him in advance if they are uncertain whether
12 to recuse.

13 Mr. Barrett explained the difference between
14 abstention and recusal, where abstention is just
15 withholding a vote and does not affect quorum
16 requirements but recusal does affect the quorum.

17 Mr. Barrett discussed conflicts of interest for
18 professional Board members, where no member of any
19 professional examining or licensing Board shall at
20 the same time be an officer or agent of a statewide
21 association or organization representing the
22 profession or occupation subject to the Board's
23 action. He also referred to conflicts of interest
24 for public members for their review.

25 Dr. Trimmer read a comment in chat from Larry

1 Jones, Pennsylvania Society of Health-System
2 Pharmacists, noting he referred to the Sunshine
3 presentation per parliamentary procedures and asked
4 whether the agenda should include a section entitled
5 public comment as well as a section moving to close
6 the agenda meeting.

7 Mr. Barrett informed Mr. Jones that a public
8 comment section would be added to the next agenda.]

9

10 Report of Board Chairperson

11 [Christine Roussel, Pharm.D., BCOP, BCSCP,
12 Chairperson, noted the sections to be discussed at
13 the regulatory workgroup were announced. She
14 mentioned anything remaining will be discussed at the
15 March session.

16 Chair Roussel announced the National Institute of
17 Occupational Safety and Health (NIOSH) released its
18 list of 2024 hazardous drugs at Christmas. She
19 recommended all pharmacists evaluate the 2024 list
20 and integrating it. She noted NIOSH went from three
21 categories of hazardous drugs to two categories of
22 hazardous drugs.]

23

24 Report of Acting Commissioner - No Report

25

1 Report of Executive Secretary - No Report

2 ***

3 Report of Board Members - No Report

4 ***

5 Discussion - Attendance at the NABP Annual Meeting -
6 May 13-16, 2025, in Fort Lauderdale, FL.

7 CHAIR ROUSSEL:

8 Would anybody like to make a motion to
9 send a number of members to be
10 acceptable?

11 MR. ESTERBROOK:

12 I make a motion that we send three
13 members to the NABP Meeting.

14 MS. GETZEY HART:

15 Second.

16 CHAIR ROUSSEL:

17 Would anybody like to discuss that? We
18 can move to a vote.

19

20 Hart, aye; Reed, aye; Esterbrook, aye;
21 Claggett, aye; Ritchie, aye; Slagle, aye;
22 Roussel, aye.

23 [The motion carried unanimously.]

24 ***

25 Discussion - ACPE Invitation for On-site Evaluation -

1 Doctor of Pharmacy program - University of
2 Pittsburgh School of Pharmacy/Discussion - ACPE
3 Invitation for On-site Evaluation - Doctor of
4 Pharmacy program - Lake Erie College of Osteopathic
5 Medicine School of Pharmacy

6 [Christine Roussel, Pharm.D., BCOP, BCSCP, reminded
7 everyone the Board of Pharmacy works with the
8 Accreditation Council for Pharmacy Education (ACPE)
9 to accredit schools of pharmacy. She noted when
10 schools of pharmacy are being surveyed that a Board
11 of Pharmacy member is welcome to attend to focus on
12 supporting ACPE and making sure they are doing a
13 thorough job in the accreditation process.

14 Chair Roussel reported two schools are upcoming
15 for accreditation, one is Lake Erie College of
16 Osteopathic Medicine School of Pharmacy, which is in
17 March in Erie, PA, and Bradenton, FL. She noted the
18 second one is for the University of Pittsburgh in
19 April.]

20 CHAIR ROUSSEL:

21 Would anybody like to make a motion?

22 MS. GETZEY HART:

23 I'll make a motion to send Eric to the
24 ACPE On-site Evaluation for the
25 University of Pittsburgh School of

1 Pharmacy.

2 CHAIR ROUSSEL:

3 Would anybody like to second that?

4 MR. REED:

5 Second.

6 CHAIR ROUSSEL:

7 Any discussion? We'll call the vote on
8 that one.

9

10 Hart, aye; Reed, aye; Esterbrook, aye;
11 Claggett, aye; Ritchie, aye; Slagle, aye;
12 Roussel, aye.

13 [The motion carried unanimously.]

14

15 CHAIR ROUSSEL:

16 Now for Lake Erie College of Osteopathic
17 Medicine. It sounds like Janet might be
18 willing to do Bradenton, FL. I know we
19 were going to discuss checking calendars.

20 MR. ESTERBROOK:

21 I make a motion that we send a
22 representative to both Florida and Erie
23 March 17-21.

24 ACTING COMMISSIONER CLAGGETT:

25 Second.

1 CHAIR ROUSSEL:

2 Any further discussion? Let's call the
3 vote.

4

5 Hart, aye; Reed, aye; Esterbrook, aye;
6 Claggett, aye; Ritchie, aye; Slagle, aye;
7 Roussel, aye.

8 [The motion carried unanimously.]

9

10 Public Comment

11 [Jill Rebuck, Executive Director, Pennsylvania
12 Society of Health-System Pharmacists, stated the
13 technician regulations are still in the process of
14 being finalized through the Independent Regulatory
15 Review Commission (IRRC), et cetera.

16 Ms. Rebuck requested the Pennsylvania Society of
17 Health-System Pharmacists (PSHP) receive information
18 regarding a Board-approved training program so that
19 all of the health systems across the state will be
20 ready if it includes employer-sponsored programs,
21 etc.

22 Ms. Rebuck also requested clarification
23 concerning technicians hired after the grandfathering
24 class dates and is hoping the technicians who have
25 been employed more than a year do not need to be

1 registered as a technician trainee.

2 Ms. Rebuck reported concern from multiple health
3 systems throughout the state regarding the unknown
4 about trainees and technician shortages. She
5 requested, during the registration process, that
6 technicians who have been employed for more than a
7 year would be able to show because of X, Y, and Z
8 that the technician would not need to be considered a
9 trainee.

10 Ms. Rebuck informed Board members that PSHP is
11 very supportive of techs being registered in the
12 state but wanted to help across the state to ensure
13 minimal confusion to the technicians themselves.

14 Marc Farrell, Esquire, Regulatory Counsel, Office
15 of Chief Counsel, Department of State, explained that
16 the the Board-approved pharmacy employer is still one
17 of the training options. He noted looking at prior
18 training and whether it is on the list, where the
19 applicant would only need to apply for a tech
20 registration.

21 Mr. Farrell mentioned the regulation will be
22 similar to the last time everyone saw it but will
23 have clarification concerning employer-based
24 training.

25 Ms. Rebuck commented that employer-based training

1 would be a large percentage since there is no state
2 available Board-approved training programs in
3 Pennsylvania. She mentioned that the Pennsylvania
4 Pharmacists Association (PPA) and PSHP are very
5 united in having more guidance and asked Mr. Farrell
6 to share the changes at the March meeting so the
7 health systems have clarity and to allow the phrase
8 technician registration to be felt in a positive way
9 forward.

10 Chair Roussel suggested having a written Q&A
11 session to add a little context, and Acting
12 Commissioner Claggett agreed.

13 Ms. Talbott commented that it was written broadly
14 because the Board did not want to approve all the
15 employer work, so the onus is on the employer to
16 defend their program.

17 Victoria Elliott, RPh, MBA, CAE, Chief Executive
18 Officer, Pennsylvania Pharmacists Association,
19 requested the last official publication of the
20 technician regulation.

21 Mr. Farrell referred Ms. Elliott to IRRC's
22 website at irrc.state.pa.us under 16A-5433.

23 Mr. Farrell informed everyone that there is
24 currently a complete hold on the delivery of final
25 regulations for all of the agencies due to the sine

1 die period. He noted the regulation will be headed
2 to IRRC and referred to upcoming IRRC meetings on
3 March 20, April 10, and May 15.

4 Mr. Farrell mentioned they would be looking at
5 the April 10, possibly May 15 meeting for approval
6 and then 45 days or so after the April 10 meeting is
7 when it would be published as final and become
8 effective. He mentioned that would start the clock
9 for a year to apply for registration.

10 Ms. Rebuck noted the tech registrations would be
11 in the opposite year as the pharmacist registrations
12 and will not be finalized until summer. She asked
13 Mr. Farrell to comment about it being an odd versus
14 an even year and how they catch up to that cycle.

15 Mr. Farrell stated they would take whatever steps
16 will result in the least amount of hardship to
17 anybody for renewals. He noted it could be over two
18 years until the next renewal.

19 Mr. Jones announced that the Pennsylvania Safety
20 Authority sent CEOs and some risk managers and
21 quality managers a notice that basically states that
22 when they are reporting system failures that
23 documentation and discrepancies of controlled
24 substances should now be classified as infrastructure
25 failure, not incidents. He also reported they are

1 looking to have documentation for all administration
2 waste or return discrepancies.

3 Mr. Jones noted the original documentation
4 claimed they wanted it within 24 hours but that the
5 Pennsylvania Safety Authority just released their
6 January newsletters and does not have a timetable of
7 24 hours on the official notice. He commented that
8 every institution will be overwhelmed with paperwork
9 if they document, research, and send them every
10 documentation failure or investigation where
11 documentation was lacking but on investigation is
12 correctable.

13 Mr. Jones also referred to the timetable for
14 research, which can be several days. He noted under
15 the Drug Enforcement Administration (DEA) rules that
16 they understand the investigation and closure of
17 these issues can take several days and write that
18 into their procedures for notification to the DEA.
19 He asked whether the Board was involved in this
20 notice or have any input on this discrepancy issue.

21 Chair Roussel expressed concern as a DEA license
22 holder for a hospital. She provided an example of a
23 click error discrepancy that could be resolved within
24 minutes, noting not all discrepancies are diversion
25 events. She mentioned their 250-bed hospital has

1 about 100 to 150 discrepancies per month. She asked
2 whether anybody knows the mechanism of communication
3 with the Patient Safety Authority.

4 Mr. Barrett stated the Board has no oversight
5 over the Patient Safety Authority because it is an
6 independent state agency but offered to look for some
7 contact information.

8 Mr. Jones addressed the problems with solving
9 discrepancies within 24 hours and believed the
10 Patient Safety Authority's intention was the issue of
11 unresolved documentation discrepancies but would like
12 to have the 24-hour time frame clarified as well.

13 Mr. Barrett offered to reach out to the Patient
14 Safety Authority and then provide information at a
15 later time.]

16 ***

17 Report of Board Counsel - Regulatory Report
18 [Marc Farrell, Esquire, Regulatory Counsel, Office of
19 Chief Counsel, Department of State, informed everyone
20 that Part III of the general revisions are the
21 regulations Board members wanted to review and
22 include in the general revisions package. He noted
23 the sections for review are pharmacists, § 27.21
24 through § 27.26; management of drug therapy, § 27.301
25 and § 27.302; and compounding regulations, § 27.601

1 through § 27.606. He also noted they were all
2 promulgated in 2019 and have not had any updates. He
3 mentioned the plan is to put together parts I, II,
4 and III for another review and vote to get the
5 package moving.

6 Chair Roussel referred to § 27.21 application for
7 examinations and licensure. She stated the National
8 Association of Boards of Pharmacy created a Uniform
9 Pharmacy Jurisprudence Examination (UPJE) Steering
10 Committee that published a report in 2024 looking at
11 the architectural framework for development of a
12 Uniform Pharmacy Jurisprudence Examination for state
13 boards of pharmacy to assess competencies.

14 Chair Roussel noted the goal was for boards of
15 pharmacy to understand the obligations and how to
16 develop and maintain them, along with understanding
17 state-specific requirements and what could be
18 applicable to all states because the federal
19 government during COVID was disappointed at the
20 barriers to interstate license portability.

21 Chair Roussel explained that the federal
22 government, in times of emergency, wanted pharmacists
23 licensed in Pennsylvania to be able to go to another
24 state to help, but all of the state-specific exams
25 were considered a barrier. She noted NABP convened a

1 group to look at the UPJE for it to be a uniform exam
2 for all states. She mentioned they have the
3 Multistate Pharmacy Jurisprudence Examination (MPJE),
4 which would make it a state-specific exam.

5 Chair Roussel noted NABP has been asking Board of
6 Pharmacy members to look at whether the questions are
7 applicable to their state and whether they could
8 create a pool of universal questions. She expressed
9 concern with Pennsylvania not being ready in times of
10 emergency because their regulations take a long time
11 to promulgate when NABP moves toward the UPJE.

12 Ms. Talbott suggested striking multistate
13 pharmacy so it is a candidate for licensure to
14 practice pharmacy by examination, applying to take
15 the North American Pharmacist Licensure Examination
16 and a jurisprudence examination identified by the
17 Board.

18 Ms. Getzey Hart commented that there are also
19 individual states that have their own examinations
20 and mandate the NABP model, which is also part of the
21 discussion of allowing students to take it earlier
22 than upon graduation but in their last year of
23 school.

24 Chair Roussel referred to a recurring theme at
25 district meetings for NABP concerning the difficulty

1 of having two licensing exams for students. She
2 noted the possibility of allowing students to take
3 the law exam in their final year of pharmacy school.
4 She also noted the opposite thought process is to do
5 away with the pharmacy law exam, which some states
6 have done.

7 Ms. Rebuck stated PSHP is very supportive of
8 moving to an exam that allows for interstate
9 portability. She mentioned that more and more
10 pharmacists are involved in multiple states and
11 health systems, and many residents every year are
12 affected by the timing of being able to take the
13 MPJE. She noted PSHP is supportive of moving to UPJE
14 and personally of the idea of pharmacy students being
15 able to take the exam prior to graduation.

16 Chair Roussel referred to § 27.21(d), where
17 affidavits of internship experience shall be filed
18 before authorization to take the exam is given. She
19 suggested changing that and the applicant. She did
20 not feel it would be prohibited by the act, and they
21 could add it into § 27.21 by adjusting (b) and (d)
22 with some language, along with adjusting (d) to only
23 be for the NAPLEX. She believed NAPLEX needs to be
24 completed upon graduation because their internship is
25 really building on that, but the law is one they

1 would be able to allow before.

2 Ms. Talbott commented that they do not need the
3 affidavits of the internship because they are
4 accepting everything from the schools, noting they
5 could strike (d).

6 Chair Roussel suggested having NAPLEX as one
7 bullet and MPJE is another under (a). She mentioned
8 students on internship would be qualified to take the
9 test and asked whether schools feel students might be
10 eligible to take the test even earlier.

11 Jonathan Ference, Pharm.D., Dean, Wilkes
12 University Nesbitt School of Pharmacy, stated they
13 are in favor of allowing student pharmacists to take
14 a jurisprudence exam, whether it be the MPJE or UPJE
15 in the future prior to graduation. He explained that
16 they would build it into their curriculum and take
17 ownership of building the timing in accordingly
18 because it is such an important barrier to licensure.

19 Chair Roussel stated it sounds like they have
20 general support for a universal law exam, noting the
21 edit would be to remove "the multistate" in front of
22 pharmacy jurisprudence exam and just put (a) and fix
23 the acronym. She mentioned the second one was to
24 allow students to take it early, noting there would
25 be specific laws for Pennsylvania when UPJE is

1 available.

2 Ms. Talbott explained that NABP will also allow
3 the state to have a state-specific module, where the
4 Board could make that mandatory as an exam. She
5 explained that Ohio has a big event for reciprocal
6 licenses, where the Board reviews all the state-
7 specific laws and continuing professional education
8 (CPE).

9 Ms. Getzey Hart believed they should have
10 something specific to Pennsylvania but agreed with
11 the UPJE overall. She mentioned that the regulations
12 will be more complicated when they answer the
13 questions because they will not be able to answer
14 they do not register or license technicians.

15 Ms. Rebuck referred to the NABP UPJE Steering
16 Committee Report, noting one of the final summary
17 recommendations is that NABP will encourage but not
18 require UPJE participating states to develop and
19 implement a supplementary plus module to teach state-
20 specific laws and regs for new licensees.

21 Ms. Rebuck noted the UPJE Steering Committee
22 mentioned the Ohio Board of Pharmacy provides a
23 series of training videos, asynchronous training that
24 pharmacists seeking reciprocity to practice in that
25 state must complete. She commented that the idea of

1 a plus module, if it could be viewed 24/7 and not
2 have to be scheduled to attend a future event, would
3 greatly be appreciated if they move forward with
4 UPJE.

5 Chair Roussel noted the options are to switch to
6 the UPJE and leave it the same time, eliminate the
7 need for a law exam altogether, allow students to
8 take the exam early, or do the plus module. She
9 mentioned considering what is reasonable for the
10 Board. She mentioned creating training and education
11 costs money and maintains a cost, because it needs to
12 be reviewed often with a third party, which may add
13 on to the license.

14 Mr. Reed asked whether there is feedback from any
15 of the states that have done nontraditional licensure
16 pathways for law that when they eliminated the exam
17 or they went to the modified pathway that their acts
18 against the license went up. He mentioned that
19 having a state that completely eliminated it and
20 nothing changed would be the path of least
21 resistance.

22 Ms. Getzey Hart commented that Michigan recently
23 eliminated it within the last year. She mentioned
24 that Arkansas has had their own in-state examination
25 for many years and really has not had any issues.

1 She noted it is all across the board as far as what
2 various states do.

3 Chair Roussel suggested UPJE plus state-specific
4 laws and regulations for new licensees to the state
5 in an asynchronous continuous education format.

6 Ms. Talbott suggested just putting a
7 jurisprudence exam as identified by the Board,
8 because the state-specific information will be part
9 of the application, which does not require a
10 regulatory process to be changed.

11 Mr. Michalowski commented that attorneys in
12 Pennsylvania and several other boards for the first
13 renewal cycle for a new licensee have to complete a
14 specific CE course, which incentivizes the CE
15 community to create courses for it, because it is
16 required of any new license, including those for
17 reciprocity or those just coming out of school.

18 Mr. Michalowski explained that someone could pass
19 the NAPLEX and the jurisprudence exam, which would be
20 the state-specific requirement and be required in the
21 first renewal period. He noted other boards put it
22 in the CE section.

23 Mr. Esterbrook asked what the difference is
24 between MPJE and UPJE with some CEs. He noted the
25 importance of protecting the public and asked what

1 the benefit of the UPJE is versus what they do now.

2 Chair Roussel explained that the benefit would be
3 for licensure portability to other states and
4 expediting people getting those licenses. She
5 provided an example, where a public emergency
6 happened in Pennsylvania and they needed people,
7 noting they could come in if they had already passed
8 a UPJE in another state.

9 Chair Roussel mentioned that if the Board decided
10 they wanted an extra module that someone could watch
11 it online in emergency time in a couple days and
12 maybe pass it or not have to do the extra CEs until
13 that renewal period if they come in for an emergency.

14 Chair Roussel commented that the federal
15 government was pushing a lot with NABP. She
16 mentioned being on the Resolutions Committee
17 representing District 2 when the resolution came
18 forward to evaluate the feasibility, noting it was
19 subsequent to federal pressures to enhance the
20 ability to practice across state lines. She stated
21 the American Society of Health-System Pharmacists
22 passed a resolution to eliminate the law exam in June
23 because no other profession has both a clinical exam
24 and a law exam.

25 Mr. Reed expressed concern with someone who

1 reciprocates to Pennsylvania right after the renewal
2 period and works for two years before completing the
3 CE, not necessarily knowing Pennsylvania-specific
4 rules.

5 Chair Roussel stated they are licensed
6 practitioners and their license is subject to
7 discipline. She also commented that she could pass
8 the NAPLEX with no problem but really had to study
9 for the law because she never worked in a retail
10 pharmacy and was not things she learned as an intern.
11 She mentioned that some of what is in the law is
12 actually not applicable to certain practice.

13 Mr. Esterbrook mentioned taking the law test in
14 Maryland 5 years ago that was 50% ostomy and durable
15 medical equipment (DME), which was something he would
16 never need. He noted many people that passed the
17 NAPLEX had trouble with the law part and did not
18 believe keeping them from being practitioners in the
19 state is worth it.

20 The question was asked as to how the Board will
21 ensure the CE contains all of the elements they
22 previously worked to maintain if they decide to
23 create a CE requirement.

24 Chair Roussel explained that they would have to
25 contract with an expert to write it, noting they

1 contract with people to write the law exams that are
2 submitted to NABP on behalf of Pennsylvania.

3 Chair Roussel noted Board members agreed to move
4 from the Multistate Pharmacy Jurisprudence Exam to
5 the Uniform Pharmacy Jurisprudence Examination.

6 Ms. Getzey Hart commented that someone going to a
7 national emergency may not be getting a license and
8 may be getting a general authorization based on
9 credentials in their home state and believed the UPJE
10 is a way to go for the portability.

11 Chair Roussel mentioned that the Board may need
12 to look at what the law regulations say about
13 requiring more of an intensive CE for the first
14 renewal cycle as a separate consideration. She
15 offered to work with Mr. Farrell concerning the
16 language and present it to the Board in March for
17 review with regards to the supplement.

18 Chair Roussel explained that instead of every
19 state having their own law exam, just like they have
20 one NAPLEX for the whole entire country, they would
21 have one law exam for the whole entire country, so
22 every person who wants to get a license in
23 Pennsylvania would have to take the UPJE, where
24 multiple states would probably ask for the same
25 thing.

1 Ms. Getzey Hart suggested that anyone who already
2 has the UPJE take the module for Pennsylvania to
3 still have part of Pennsylvania.

4 It was suggested inserting Board-approved
5 Pharmacy Jurisprudence when they remove multistate.

6 Chair Roussel also noted everybody thought it was
7 acceptable to take the exam when a student is
8 eligible to do a pharmacy internship, which would be
9 the term Advanced Pharmacy Practice Experience
10 (APPE).

11 Mr. Farrell will come back again so everybody has
12 a chance to provide input and review the language.

13 Chair Roussel noted qualifications for pharmacy
14 state licensure in Pennsylvania almost allows a
15 student to fail NAPLEX once and then they are
16 referred to the Board if they fail a third time. She
17 stated there is nothing in their regulations that
18 gives the Board guidance to prohibit them from taking
19 it.

20 Chair Roussel referred to the National
21 Association of Boards of Pharmacy Model Practice Act
22 regarding qualifications for pharmacist's licensure
23 by examination under Section 302, have successfully
24 passed an examination or examinations approved by the
25 board within five attempts.

1 Chair Roussel believed there should be a limit on
2 the number of attempts to pass the exam.

3 Ms. Talbott noted that the Board currently
4 requests that the individual prove their remediation
5 before being permitted to take the test again if
6 approaching the Board for the fourth time.

7 Dr. Ference stated Wilkes University has not
8 addressed this issue with a graduate but would offer
9 NAPLEX remediation.

10 Mr. Barrett referred to the language in their
11 act, where in case of failure at a first examination,
12 applicant shall have within 2 years the privilege of
13 the second and third examination; and in the case of
14 failure in a third examination, the applicant shall
15 have the privilege of examination only after
16 satisfactorily completing additional preparation as
17 directed and approved by the Board. He expressed
18 concern with imposing a concrete cap on the number of
19 times someone can take the exam.

20 Acting Commissioner Claggett commented that he is
21 not in favor of a hard cap and to keep it as is.

22 Chair Roussel noted § 27.21 through § 27.25
23 covered application for examination and licensure,
24 required license exams, application for expulsion,
25 time and place for holding exams, examination and

1 passing scores, and licensure by reciprocity.

2 Ms. Talbott stated whatever § 27.21 will be will
3 dictate the remaining language in the section,
4 because the verbiage about UPJE, Federal Drug Law
5 Examination (FDLE), and reciprocity would have to
6 change.

7 Mr. Farrell noted the Board's Act 41 regulations
8 are still in the pipeline and will go between § 27.25
9 and § 27.26.

10 Mr. Farrell referred to § 27.26, noting it is
11 part of general revision Part I, and changes made in
12 Part I of the general revisions package would appear
13 on the document at (a)(5). He noted the striking of
14 (d)(3) and removing the words "up to 1,000 of the" in
15 (d)(4).

16 Mr. Ference referred to § 27.26(b), completed at
17 least 2 years of college and is enrolled or accepted
18 as a student in an ACPE-accredited school. He noted
19 being a 2-4-year program and seeing more and more
20 students with dual enrolls in high school and
21 Advanced Placement (AP) credits doing a 1-year pre-
22 pharmacy and suggested the wording be changed to
23 completing at least 2 years of college credits or 60
24 college credits as opposed to 2 years on the
25 calendar.

1 Chair Roussel addressed a situation where
2 somebody from a college of pharmacy had a young
3 genius around 15 or 16 and wanted to change the age
4 requirement. She discussed asking for a waiver if a
5 child genius wanted to be a pharmacist.

6 Chair Roussel referred to § 27.301 and § 27.302
7 regarding management of drug therapy. She reported
8 barriers with the Pennsylvania Licensing System
9 (PALS) that affect the way some of the documentation
10 is put forward.

11 Ms. Rebuck referred to § 27.301(6), statement
12 that requires notification. She noted using
13 electronic medical records compared to when these
14 were written, which is communicated seamlessly and
15 shared with all involved in the care of the patients.
16 She suggested changing (6) to include the phrase,
17 when a shared electronic medical record is not in
18 use, then a statement that requires notification.

19 Ms. Rebuck referred to (9), the signatures of the
20 physicians and pharmacists who are entering in the
21 written protocol and the date signed. She noted
22 removing the period and add must be obtained
23 electronically or in writing.

24 Mr. Jones referred to § 27.301(6), where it says
25 authorizing physician. He noted the definition of

1 provider is certainly much greater than a physician
2 and is causing issues with extended providers. He
3 believed the phrase should say authorizing
4 provider/physician to meet the definition
5 Pennsylvania uses in all of their other statutes as
6 well.

7 Mr. Farrell recommending leaving it as
8 authorizing physician or provider.

9 Ms. Rebuck suggested the addition of § 27.301(f),
10 noting there is a paragraph within the act, which
11 reads managing blood therapy within an institutional
12 setting may occur without the requirements of
13 subsection (e), provided it is pursuant to a medical
14 order by a licensed physician for managing drug
15 therapy protocol approved by the medical staff of the
16 institution.

17 Ms. Rebuck stated they interpret what is listed
18 in the act, and it is just for completeness. She
19 noted it is based in the institutional setting and is
20 basically saying management of drug therapy within an
21 institutional setting provided pursuant to a medical
22 order by a licensed physician for managing drug
23 therapy protocols approved by the medical staff of
24 the institution. She provided an example.

25 Ms. Rebuck referred to § 27.302(f)(1) and

1 suggested making (f)(1) and (f)(2) physicians and
2 pharmacists or placing an (s) after physician and
3 pharmacist because there are more than one physician
4 and one pharmacist involved in performing the
5 activity.

6 Ms. Rebuck referred to (f)(3), the collaborative
7 practice agreement must contain, and suggested
8 leaving the first four words, a statement requiring
9 that and then cross out the rest of that sentence and
10 change it to a statement requiring that a physician
11 initiate the management of drug therapy with referral
12 to a pharmacist.

13 Chair Roussel commented that it is not changing
14 the intent but makes more sense.

15 Ms. Rebuck referred to (f)(7), a statement that
16 requires notification of the authorizing physician.
17 She suggested removing the period at the end, where
18 it says change and add when a shared electronic
19 medical record is not in use for it to read, a
20 statement that requires notification to the
21 authorizing physician of change in dose, duration, or
22 frequency of medication prescribed as soon as
23 applicable but no longer than 72 hours after change.
24 She noted that addition, when a shared electronic
25 medical record is not in use.

1 Chair Roussel mentioned that it might be a
2 section where the statement could also include
3 authorizing physician or provider in addition to that
4 change.

5 Ms. Rebuck referred to (f)(10) and suggested
6 adding to the end of the sentence for it to read, the
7 signatures of the physicians and pharmacists who are
8 entering into the collaborative agreement and the
9 date signed must be obtained electronically or in
10 writing.

11 Ms. Talbott suggested putting electronic or
12 physical in front of signatures.

13 Chair Roussel recommended being consistent with
14 prior changes.

15 Ms. Rebuck suggested adding a second sentence to
16 (f)(10), signatures of physician and/or pharmacist
17 leader on their behalf are permitted. She noted they
18 are talking about a chief medical officer, the head
19 of a clinic, a pharmacy clinical director, who is the
20 individual who is involved in the responsibilities
21 with the collaborative agreement as the employer of
22 those individual physicians or pharmacists.

23 Mr. Jones explained that as different protocols
24 come available and as they are initiated, depending
25 on the streamlining of patient care, the search for

1 providers can be cumbersome and provided an example.

2 Chair Roussel added that there is formal
3 committee structured for those approvals and agreed
4 that administrative burden is intense.

5 Ms. Rebuck mentioned that they were being
6 respectful of colleagues beyond the health system
7 when they chose the verbiage of leaders because a
8 health system will have a director, but there may not
9 always be a director present in some other clinics.
10 She stated it is clearly the pharmacist leader of
11 that area who is responsible for employees who have
12 been vetted through those groups. She noted PSHP
13 strongly supports this, along with several colleagues
14 around the state who would be very appreciative if
15 that was added.

16 Chair Roussel suggested it read, pharmacists with
17 administrative authority over the practice site.

18 Ms. Rebuck requested approval for it to read,
19 signatures of physician and/or pharmacist leader with
20 administrative authority over the practice site,
21 noting the intent is the physician leader of that
22 area has direct oversight over those individuals.

23 Chair Roussel suggested administrative authority
24 over practice site or medical service line because
25 the whole thing is a cardiology protocol across all

1 cards.

2 Ms. Rebuck confirmed for it to read, signatures
3 of physician and/or pharmacist leaders with
4 administrative authority over the practice site or
5 medical service line are permitted. She referred to
6 (f)(10), the signatures of the physicians and
7 pharmacists who are entering the collaborative
8 agreement and the dates signed with the addition of
9 must be obtained electronically or in writing.
10 Signatures of physician and/or pharmacist leaders
11 authorized with administrative authority over the
12 practice site or service line on their behalf are
13 permitted.

14 Ms. Talbott commented that she could clean it up
15 in the front, where they talked about the electronic
16 or physical signature that was like the first change.
17 and then the physician and/or pharmacist leaders'
18 administrative authority over the practice site or
19 service line.

20 Ms. Rebuck referred to § 27.302(4)(h) and for it
21 to read, the collaborative agreement shall be filed
22 with the Bureau (Board), submitted electronically by
23 the individual pharmacist for an authorized designee
24 or as a batch file for pharmacists under the same
25 employer.

1 Ms. Rebuck wanted to have them move to submitting
2 electronically by the individual pharmacist because
3 sometimes the pharmacist is only involved but could
4 be part of a much larger group of collaborative
5 agreements and much larger number of pharmacists. So
6 to decrease the board's administrative burden and the
7 site's administrative burden, have it submitted
8 electronically by that individual pharmacist or an
9 authorized designee or as a batch file for
10 pharmacists under the same employer. She mentioned
11 that having 12 pharmacists at a site who may have 5
12 practice agreements would be 12 times 5 files
13 uploaded versus 1 batch file that can be sent by
14 someone authorized on that behalf.

15 Ms. Talbott was not sure that it had to be
16 uploaded is in the act because it says upon request
17 to represent you have provided it to representatives
18 of the State Board of Medicine, State of Osteopathic
19 Medicine, State of Pharmacy, and the Department of
20 State.

21 Ms. Rebuck noted the current state in practice is
22 required to be uploaded.

23 Ms. Talbott stated it is in the regulations that
24 it shall be filed with the Bureau but did not believe
25 it is in the statute, so they could take out (h) and

1 add it to (4) upon request, to representatives of the
2 Bureau and the Department of Health.

3 Ms. Rebuck confirmed striking (h), the
4 collaborative agreement shall be filed with the
5 Bureau, which would decrease everyone's
6 administrative burden. She noted it would still be
7 available in (g)(1) through (4).

8 Ms. Rebuck suggested § 27.302(k)(2) read,
9 initiate the management of drug therapy only upon a
10 written referral to the pharmacist from the
11 physician, either for an individual patient or for a
12 group of patients based on protocol.

13 Chair Roussel suggested removing the word
14 "written" and adding provider.

15 Chair Roussel referred to § 27.601 regarding
16 compounding.

17 Ms. Rebuck recommended § 27.605 read, the label
18 affixed to or on the dispensing container of a
19 compounded drug product dispensed by a pharmacy
20 pursuant to a prescription or drug order must bear
21 the information as required under current USP
22 regulations.

23 Ms. Talbott noted IRRC had the Board put § 27.18
24 back in.

25 Mr. Jones noted § 27.18(d) was established 15 to

1 20 years ago. He explained in 2017, § 27.18 added
2 (v) for inpatient institutional uses that made
3 exceptions to what was required under section (d) for
4 IVs totally consumed on site. He mentioned they do
5 not need the DEA number, address, and some of the
6 other things.

7 Ms. Talbott noted they could fix § 27.18(v) and
8 § 27.18(d).

9 Ms. Rebuck referred to § 27.26(h)(4) regarding
10 pharmacy interns, where a pharmacy shall compound and
11 dispense a sufficient number of prescriptions,
12 including renewals so as to provide the pharmacy
13 intern with ample opportunity to scrutinize
14 prescriptions and to compound dispense under the
15 supervision of a licensed pharmacy.

16 Ms. Rebuck asked the Board for a sufficient
17 minimum number or whether they should just remove it.

18 Ms. Talbott explained that the intent was so
19 interns were not filling two prescriptions a day and
20 not getting any knowledge. She recommended not
21 changing anything.

22 Chair Roussel asked whether PSHP believed
23 nonsterile compounders read the Federal Food, Drug,
24 and Cosmetic Act regarding 503A compounding
25 standards. She explained that the FDA has a list of

1 drugs not approved for bulk compounding and specific
2 requirements about drugs that do not have a United
3 States Pharmacopeia (USP) monograph for compounding,
4 where she believed it did not need to be put in
5 there.

6 Chair Roussel also asked Mr. Michalowski to ask
7 inspectors whether people are compounding things
8 without a USP monograph and have been withdrawn from
9 the FDA market because of safety. She mentioned the
10 most common FDA finding is that people are
11 compounding with ingredients on the lists but do not
12 know they are not allowed to use them.

13 Ms. Elliott commented that the Board is
14 reluctant, unlike other boards, to provide guidance
15 on their own regulations when they want people to
16 conform.

17 Mr. Barrett stated there is case law that the
18 Board cannot reprove conduct or issue advisory
19 opinions because they are not authorized under their
20 Practice Act to do so. He noted other states have
21 more explicit guidelines where the boards can give
22 opinions. He mentioned there was a bill introduced
23 to make it so the Board is required to issue advisory
24 opinions but was not sure whether that would ever
25 happen.

1 Chair Roussel commented that it is everyone's
2 responsibility to be proactive, including the law
3 exam, where they should be taking extra steps to read
4 things applicable to their practice areas.

5 Chair Roussel stated the draft edits of the same
6 sections would be provided in advance of the March
7 meeting for review.

8 Mr. Jones commented that the caveat of the three
9 sections is that they are presuming the law is
10 changing for everything applicable to the new format
11 for printing out their own licenses and no longer
12 receiving a wallet card. He noted they are not in
13 the Pharmacy Act itself but are in other sections of
14 Chapter 49 and offered to send Chair Roussel the
15 lists.

16 Ms. Elliott thanked the Board for the timeline
17 concerning the regulations. She reported receiving
18 calls at their office from people being referred by
19 the Board. She noted much confusion around when the
20 technician regulations would be promulgated from new
21 technicians and employers.

22 Dr. Trimmer explained that anyone requesting
23 information would be told the regulations are in the
24 pipeline and will be posted as soon as available.]

25

1 Adjournment

2 CHAIR ROUSSEL:

3 Anyone want to make a motion to adjourn?

4 MS. GETZEY HART:

5 I make a motion to adjourn.

6 ***

7 [There being no further business, the State Board of
8 Pharmacy Meeting adjourned at 1:21 p.m.]

9 ***

10

11 CERTIFICATE

12

13 I hereby certify that the foregoing summary
14 minutes of the State Board of Pharmacy meeting, was
15 reduced to writing by me or under my supervision and
16 the minutes accurately summarize the substance of the
17 State Board of Pharmacy meeting.

18

19



20

Allison Walker,

21

Minute Clerk

22

Sargent's Court Reporting

23

Service, Inc.

24

25

26

STATE BOARD OF PHARMACY
REFERENCE INDEX

January 21, 2025

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TIME	AGENDA
9:00	Executive Session
10:30	Return to Open Session
10:32	Official Call to Order
10:32	Introduction of Board Members/Attendees
10:33	Approval of Minutes
10:35	Report of Board Counsel
10:37	Review of Applications
10:41	Appointment - Annual Prosecution Report
11:10	Report of Board Chairperson
11:12	Discussion
11:17	Public Comment
11:31	Report of Board Counsel (cont.)
1:21	Adjournment