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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: 10:30 A.M.

Held at

**PENNSYLVANIA DEPARTMENT OF STATE**

Wilkes University  
Nesbitt School of Pharmacy  
Stark Learning Center  
84 West South Street  
Wilkes-Barre, PA 18766

as well as

**VIA MICROSOFT TEAMS**

October 22, 2024

State Board of Pharmacy  
October 22, 2024

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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  
Marc Farrell, Esquire, Regulatory Counsel,  
Office of Chief Counsel, Department of State  
Nathan C. Giunta, Esquire, Board Prosecution Liaison  
Caroline A. Bailey, Esquire, Board Prosecutor  
Tyesha C. Miley, Esquire, Board Prosecutor  
Sara Trimmer, Pharm.D., R.Ph., Executive Secretary  
Nichole Wray, Division Chief, Health Licensing  
Division  
Andrew LaFratte, MPA, Deputy Policy Director,  
Department of State  
Michael P. Merten, Esquire, Board Counsel, State  
Board of Barber Examiners  
Steven Zahn, Pharmacy Inspector, Bureau of  
Enforcement and Investigation, Department of State  
Elle Thompson, Law Clerk, PA Department of State

ALSO PRESENT:

Theresa M. Talbott, R.Ph., Director, Pharmacy and  
Retail Advocacy, CVS Pharmacy  
Katie, Walgreens Pharmacy  
Letitia Warunek, PharmD, Assistant Professor of  
Pharmacy Practice at Wilkes University  
Morgan McIntyre, Pharmacy Student, Wilkes University  
Toni McDonald, PharmD, MBA, Chewy Pharmacy  
Larry Jones, Pennsylvania Society of Health-System  
Pharmacists Member

State Board of Pharmacy  
October 22, 2024

ALSO PRESENT: (cont.)

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7 Jill Rebeck, Executive Director, Pennsylvania Society  
8 of Health-System Pharmacists  
9 Nicole, CVS Health  
10 Paul, Student, Wilkes University  
11 Julie Olenak, Admissions and Student Affairs, Wilkes  
12 University  
13 Danielle Keith, Faculty, Wilkes University  
14 Nicole Pezzino, Wilkes University  
15 Grace O'Toole, Student, Wilkes University  
16 Archie, Student, Wilkes University  
17 Brett Rodgers, Senior Manager for Pharmacy  
18 Automation, University of Pittsburgh Medical Center  
19 Steven L. Sheaffer, PharmD, FASHP, Pennsylvania  
20 Society of Health-System Pharmacists  
21 Jonathan Ference, Dean, Nesbitt School of Pharmacy,  
22 Wilkes University  
23 Brittany  
24 Rebecca Taylor, Pharm.D., Vice President, Pharmacy  
25 Services, University of Pittsburgh Medical Center  
26 Regan Ceraso, RPh, BPharm, Quality Director, Medical  
27 - Health Professions Program, Carnegie Mellon  
28 University  
29 Natalie Klek, Executive Fellow, Pennsylvania  
30 Pharmacists Association  
31 Geoffrey Christ, Senior Pharmacy Compliance Manager,  
32 Chewy Pharmacy  
33 Michelle Aytay, Manager, Pharmacy Affairs, Walgreens  
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 James Maister  
39 Christina Antoun Pharmacy Licensing, Research, and  
40 Regulatory Affairs, REAL Solutions Group LLC  
41 Susan DelMonico, R.Ph., JD  
42 Sarah Everingham, MJ, CCEP, CPhT, Cardinal Health  
43 Joshua Finger, PharmD, Enclara Pharmacia  
44 Grace Fisher, Regional Pharmacy Manager, Giant Food  
45 Stores, LLC  
46 Jacquelyn Sassaman, Pentec Health  
47 Ultan McGlone, Pharmacist Clinician/Clinical  
48 Pharmacy Specialist  
49 Megan Ammon, PharmD, BCMTMS, Clinical Program  
50 Coordinator at Weis Markets  
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State Board of Pharmacy  
October 22, 2024

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ALSO PRESENT: (cont.)

- Christopher Miller, Pharm.D., Giant Eagle
- Nicole Fidler, Associate, Malady & Wooten
- Misha Patel, M.D., Curriculum Education Assistant,  
Geisinger Commonwealth School of Medicine
- Laura Romeo, Pharmacist-in-Charge at ConnectiveRx,  
Careform Pharmacy
- Cory Ulisse, PharmD, Pharmacy Clinician Services
- David Klinger, RPh, Director of Pharmacy, Geisinger  
Medical Center
- Jennifer Smeltz, Republican Executive Director,  
Senate Consumer Protection & Professional Licensure  
Committee
- Charlotte Harris, Student at Duquesne University
- Sarada Vanguri
- Emily George, PharmD, Penn Medicine
- Judy Kutchman, R.Ph., AllianceRx Walgreens Prime
- Charlotte Olivia Nazar, Pharmacy Intern at Harrisburg  
Pharmacy
- Joseph Millward, Pharmacy Quality and Accreditation,  
PANTHERx Rare Pharmacy
- Dawn Cardamone, Express Scripts
- Kimmy Nguyen, PharmD, Associate Professor, Pharmacy  
Practice, Wilkes University
- Victoria Elliott, RPh, MBA, CAE, Chief Executive  
Officer, Pennsylvania Pharmacists Association
- Adam VanWert, PharmD, PhD, WebMD
- David Rubin, Esquire, Rubin & Rubin
- Sean
- Ryan
- JML
- Samantha Bruer, Sargent's Court Reporting Service,  
Inc.

1 \*\*\*

2 State Board of Pharmacy

3 October 22, 2024

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, October 22,  
15 2024. Christine Roussel, Pharm.D., BCOP, BCSCP,  
16 Chairperson, called the meeting to order at  
17 10:30 a.m.

18 \*\*\*

19 Introduction of Board Members/Attendees  
20 [Chair Roussel requested an introduction of Board  
21 members and attendees. A quorum of Board members was  
22 present.]

23 \*\*\*

24 [Sean C. Barrett, Esquire, Board Counsel, informed  
25 everyone that the meeting was being recorded, and

1 those who continued to participate were giving their  
2 consent to be 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 Agenda

10 CHAIR ROUSSEL:

11 The first item on our agenda is approval  
12 of the agenda.

13 Was there any amendments or any  
14 changes to the agenda?

15 MR. BARRETT:

16 The agenda does say Theresa Talbott is  
17 still a member and does not have the  
18 addition of Jim Reed.

19 MR. ESTERBROOK:

20 I will make a motion to approve the  
21 revised agenda.

22 MS. GETZEY HART:

23 Second.

24 CHAIR ROUSSEL:

25 Any further discussion? We'll call the

1 vote.

2

3 Hart, aye; Reed, aye; Esterbrook, aye;  
4 Claggett, aye; Slagle, aye; Ritchie, aye;  
5 Roussel, aye.

6 [The motion carried unanimously.]

7

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8 Approval of Minutes

9 CHAIR ROUSSEL:

10 Next is the approval of minutes for  
11 August 27, 2024.

12 Any edits or amendments?

13 MR. ESTERBROOK:

14 Motion to approve the minutes.

15 MS. GETZEY HART:

16 Second.

17 CHAIR ROUSSEL:

18 Any further discussion? Let's call the  
19 votes for approval of the August 27, 2024  
20 minutes.

21

22 Hart, aye; Reed, abstain; Esterbrook,  
23 aye; Claggett, aye; Ritchie, aye; Slagle,  
24 aye; Roussel, aye.

25 [The motion carried. James Reed abstained from

1 voting on the motion.]

2 \*\*\*

3 Report of Board Prosecution

4 [Nathan C. Giunta, Esquire, Board Prosecution  
5 Liaison, on behalf of Ashley Murphy, Esquire, Board  
6 Prosecutor, presented the Consent Agreement for Case  
7 No. 24-54-001689.]

8 \*\*\*

9 [Nathan C. Giunta, Esquire, Board Prosecution  
10 Liaison, presented the Consent Agreements for Case  
11 No. 22-54-007530, Case No. 22-54-014770, Case No. 23-  
12 54-015380, and Case Nos. 24-54-012958 & 24-54-  
13 012959.]

14 \*\*\*

15 [Nathan C. Giunta, Esquire, Board Prosecution  
16 Liaison, on behalf of Ray Michalowski, Esquire,  
17 Senior Board Prosecutor, presented the Consent  
18 Agreement for Case No. 24-54-014571.]

19 MR. BARRETT:

20 Based on Executive Session deliberations,  
21 I believe the Board Chair would entertain  
22 a motion to approve the Consent Agreement  
23 at Case No. 24-54-001689. Jim Reed did  
24 recuse himself from any deliberations in  
25 this matter.



1 MR. ESTERBROOK:

2 So moved.

3 ACTING COMMISSIONER CLAGGETT:

4 Second.

5 CHAIR ROUSSEL:

6 Any further discussion? Let's call the  
7 vote.

8

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

12 [The motion carried. James Reed recused himself from  
13 deliberations and voting on the motion. The  
14 Respondent's name is Vinh D. Pham, R.Ph.]

15 \*\*\*

16 MR. BARRETT:

17 Based on Executive Session deliberations,  
18 I believe the Board Chair would entertain  
19 a motion to approve the Consent Agreement  
20 at item 3, Case No. 22-54-007530.

21 MR. ESTERBROOK:

22 So moved.

23 ACTING COMMISSIONER CLAGGETT:

24 Second.

25 CHAIR ROUSSEL:

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

3  
4 Hart, aye; Reed, abstain; Esterbrook,  
5 aye; Claggett, aye; Ritchie, aye; Slagle,  
6 aye; Roussel, aye.

7 [The motion carried. James Reed abstained from  
8 voting on the motion. The Respondent's name is  
9 Nicholas Kernick.]

10 \*\*\*

11 MR. BARRETT:

12 Item 4, Case No. 22-54-014770. Based on  
13 Executive Session deliberations, I  
14 believe the Board Chair would entertain a  
15 motion to reject the Consent Agreement as  
16 too lenient.

17 MR. ESTERBROOK:

18 So moved.

19 ACTING COMMISSIONER CLAGGETT:

20 Second.

21 CHAIR ROUSSEL:

22 Any further discussion? Let's call the  
23 vote.

24  
25 Hart, aye; Reed, abstain; Esterbrook,



1 MR. BARRETT:

2 Item 6, Case Nos. 24-54-012958 & 24-54-  
3 012959. Based on Executive Session  
4 deliberations, I believe the Board Chair  
5 would entertain a motion to approve the  
6 Consent Agreement at those numbers.

7 MR. ESTERBROOK:

8 So moved.

9 ACTING COMMISSIONER CLAGGETT:

10 Second.

11 CHAIR ROUSSEL:

12 Any discussion? Let's call the vote.

13

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

17 [The motion carried. James Reed abstained from  
18 voting on the motion. The Respondents are James  
19 Rulyak and McKeesport Prescription Center.]

20

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21 MR. BARRETT:

22 Item 7, Case No. 24-54-014571. Based on  
23 Executive Session deliberations, I  
24 believe the Board Chair would entertain a  
25 motion to approve the Consent Agreement.

1 MR. ESTERBROOK:

2                   So moved.

3 ACTING COMMISSIONER CLAGGETT:

4                   Second.

5 CHAIR ROUSSEL:

6                   Any discussion? Let's call the vote.

7

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

11 [The motion carried. James Reed abstained from  
12 voting on the motion.]

13

\*\*\*

14 [Nathan C. Giunta, Esquire, Board Prosecution  
15 Liaison, provided an overview of the prosecutorial  
16 division. He explained that there are a group of  
17 prosecutors under the Department of State who cover  
18 and enforce the acts and regulations of the 32  
19 different professional licenses across the  
20 Commonwealth of Pennsylvania.

21                  Mr. Giunta noted several prosecutors are charged  
22 with dealing with all of the pharmacy complaint  
23 investigations and deciding whether or not they  
24 amount or arise to a violation of the act or  
25 regulations. He provided a summary of the

1 prosecutorial process from the time the complaint is  
2 received, investigations through the Bureau of  
3 Enforcement and Investigation, review of reports from  
4 prosecution, and whether the conduct violated the act  
5 or regulations. He also provided a scenario of an  
6 individual who is a pharmacist in Ohio and  
7 Pennsylvania but received discipline for a violation  
8 in Ohio.

9 Mr. Giunta addressed Act 53 regarding crimes  
10 directly related to the profession, including  
11 overprescribing, dispensing, and Medicaid fraud.

12 Mr. Giunta discussed the Voluntary Recovery  
13 Program (VRP) for licensed professionals. He  
14 reported 90% of it relates to the healthcare  
15 profession boards. He explained that the program is  
16 for addiction issues and similar to a criminal  
17 version of the Accelerated Rehabilitative Disposition  
18 (ARD) Program.

19 Mr. Giunta noted the program is confidential and  
20 usually about a three-year term of monitoring that  
21 can be removed from the licensee's record following  
22 successful completion of the program. He mentioned  
23 that the program is utilized by the medical boards,  
24 including pharmacy, medical, dental, and  
25 veterinarian.

1           Mr. Giunta explained that even though prosecution  
2 is separate from the Board that it is prosecution's  
3 job to enforce its rules and regulations.

4           Chair Roussel commented that it is the role of  
5 the Board to decide after hearing the cases to accept  
6 the cases and the discipline that has been negotiated  
7 or reject them as either too lenient or too harsh.  
8 She noted the importance of being consistent in the  
9 fines or punishment with previous situations  
10 regarding licenses.

11           Mr. Giunta explained that it is not like a  
12 criminal sentencing guideline that says if they have  
13 been charged with this offense and have never been in  
14 trouble that a judge can give this sentence. He  
15 further explained that the acts and regulations do  
16 not provide that unless it is a citation, where in  
17 some of the cases they are enforcing and offering  
18 punishment based on the Board's prior decisions to  
19 accept or reject.

20           Mr. Giunta mentioned that if he cannot figure out  
21 what the Board wants after presenting the case twice  
22 that the matter will go to a hearing. He noted that  
23 prosecution tries to be very consistent to what the  
24 Board has done in the past to be fair to everyone.]

25

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1 Report of Board Counsel - Proposed Adjudication and  
2 Order

3 MR. BARRETT:

4 At item 9, based on Executive Session  
5 deliberations, I believe the Board Chair  
6 would entertain a motion to adopt the  
7 Proposed Adjudication and Order at Case  
8 No. 24-54-007440. Tyler Ritchie was  
9 recused from any discussion and  
10 deliberation on this matter.

11 MR. ESTERBROOK:

12 So moved.

13 ACTING COMMISSIONER CLAGGETT:

14 Second.

15 CHAIR ROUSSEL:

16 Any discussion? Let's call the vote.

17

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

21 [The motion carried. Tyler Ritchie recused himself  
22 from deliberations and voting on the motion. James  
23 Reed abstained from voting on the motion. The  
24 Respondent's name is Laurel F. Scicchitano, R.Ph.]

25

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1 Report of Board Counsel - Final Adjudication and  
2 Order

3 MR. BARRETT:

4 At item 10, based on Executive Session  
5 discussions, I believe the Board Chair  
6 would entertain a motion to approve the  
7 Adjudication and Order at Case No. 23-54-  
8 016668.

9 MR. ESTERBROOK:

10 So moved.

11 ACTING COMMISSIONER CLAGGETT:

12 Second.

13 CHAIR ROUSSEL:

14 Any discussion? Let's call the vote.

15

16 Hart, aye; Reed, abstain; Esterbrook,  
17 aye; Claggett, aye; Ritchie, aye; Slagle,  
18 aye; Roussel, aye.

19 [The motion carried. James Reed abstained from  
20 voting on the motion. The Respondent's name is  
21 Ihsanullah Maaf.]

22

\*\*\*

23 Report of Board Chairperson

24 [Christine Roussel, Pharm.D., BCOP, BCSCP,

25 Chairperson, addressed her attendance, along with Mr.

1 Esterbrook, at the National Association of Boards of  
2 Pharmacy in October 2024 as representatives for  
3 Pennsylvania. She noted the National Association of  
4 Boards of Pharmacy and the American Association of  
5 Colleges of Pharmacy (AACCP) have a joint meeting for  
6 Districts 1 and 2 that stretches from Virginia to  
7 Ontario for the representatives to share ideas and  
8 discuss how to improve the profession.

9 Chair Roussel highlighted a 1-hour session, where  
10 Al Carter, who is the current executive for NABP,  
11 talked about the Uniform Pharmacy Jurisprudence  
12 Examination (UPJE), which would be a single exam that  
13 students would take regardless of what states they  
14 were in.

15 Chair Roussel noted there was also discussion  
16 about whether they should continue with the law exam  
17 or whether there should be other opportunities for  
18 doing the law exam before students graduate. She  
19 mentioned additional information and insight for more  
20 informed discussions when discussing the license  
21 section of their regulations in early 2025.

22 Chair Roussel also reported many sessions  
23 highlighted practice advancement in other states,  
24 including pharmacists writing for hormone  
25 contraceptives.

1 Ms. Getzey Hart commented, in addition to serving  
2 on the Pennsylvania Board of Pharmacy, there is the  
3 ability to serve on the executive committee for the  
4 National Association of Boards of Pharmacy. She  
5 reported eight districts throughout the country that  
6 representatives can get elected to represent their  
7 district.

8 Chair Roussel announced NABP Districts 1 and 2  
9 will be hosted in Philadelphia October 15-17, 2025,  
10 by the Pennsylvania Board of Pharmacy. She reported  
11 being excited and looked forward to a robust agenda  
12 to include discussing how pharmacists can help  
13 mitigate healthcare disparities through their  
14 activities. She mentioned it to be a combination of  
15 deans, board of pharmacy members, and the schools all  
16 together.

17 Chair Roussel acknowledged Board member Terry  
18 Talbot, who had her last meeting on the Board in  
19 August 2024 and honored her by giving her a gavel.  
20 She noted Ms. Talbott was a member on the Board from  
21 2011 to 2024 and has been with CVS for approximately  
22 35 years.

23 Chair Roussel also mentioned Ms. Talbott was an  
24 honorary president for the National Association of  
25 Boards of Pharmacy and won the Carmen A. Catizone

1 Honorary President Award. She thanked Ms. Talbott  
2 for her service to the State Board of Pharmacy and  
3 all that she has done for patients, pharmacists, and  
4 other entities to advance patient safety and the  
5 practice of pharmacy.

6 Chair Roussel noted Ms. Talbott's knowledge of  
7 regulations across multiple states is unparalleled,  
8 and she has done so much for the NABP Model Practice  
9 Act, which is used as examples to form their state  
10 regulations. She mentioned Ms. Talbott has been a  
11 strong representative of the values and mission of  
12 the Pennsylvania State Board of Pharmacy and the  
13 national boards. She thanked her for her service to  
14 the Board and looked forward to Ms. Talbott at future  
15 meetings.

16 Chair Roussel stated appointments to the Board  
17 are six years and is a slightly complex process,  
18 because they have to work with their state senator  
19 and get a recommendation to the Governor. She noted  
20 the Governor's Office is the one who makes the formal  
21 nomination to the Senate.

22 Chair Roussel welcomed new Board member Jim Reed  
23 to the Pennsylvania State Board of Pharmacy.

24 Mr. Reed provided a brief summary of his  
25 professional background.]

1 \*\*\*

2 Report of Acting Commissioner

3 [Arion R. Claggett, Acting Commissioner, Bureau of  
4 Professional and Occupational, informed Board members  
5 that a vendor was selected for replacement of the  
6 Pennsylvania Licensing System (PALS), and System  
7 Automation would be implemented at the end of 2025.

8 Chair Roussel requested an update concerning  
9 licensure approvals. She noted the licensure period  
10 closed but believed it was successful with positive  
11 feedback.

12 Dr. Trimmer reported 95% of renewals were  
13 completed with 1% on inactive status.

14 Chair Roussel noted hearing one complaint that  
15 the new visual look of the licensing was not as  
16 pretty, and they missed the colors.

17 Acting Commissioner Claggett mentioned that  
18 people complained when it was blue and are now  
19 complaining it is white paper. He explained that the  
20 best thing about the new version is licenses could be  
21 printed out by licensees.

22 Chair Roussel commented that feedback from  
23 licensees being able to print licenses themselves has  
24 been overwhelmingly positive and amazing.]

25 \*\*\*

1 Report of Executive Secretary

2 [Sara Trimmer, Pharm.D., R.Ph., Executive Secretary,  
3 again reported that renewals went smoothly with 95%  
4 of renewals completed and 1% on inactive status.]

5 \*\*\*

6 Review of Applications

7 MR. BARRETT:

8 Item 11 on the agenda. Based on  
9 Executive Session deliberations, I  
10 believe the Board Chair would entertain a  
11 motion to approve the processing of the  
12 Application of James Maister.

13 MR. ESTERBROOK:

14 So moved.

15 ACTING COMMISSIONER CLAGGETT:

16 Second.

17 CHAIR ROUSSEL:

18 Any discussion? Let's call the vote.

19

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

23 [The motion carried. James Reed abstained from  
24 voting on the motion.]

25 \*\*\*

1 Correspondence - ACPE Invitation for On-site  
2 Evaluation - Doctor of Pharmacy Program - Temple  
3 University School of Pharmacy November 12-14, 2024  
4 [Christine Roussel, Pharm.D., BCOP, BCSCP,  
5 Chairperson, announced that the Board has received an  
6 invitation from the Accreditation Council for  
7 Pharmacy Education (ACPE) for an on-site evaluation  
8 for the Temple University School of Pharmacy's Doctor  
9 of Pharmacy Program November 12-14, 2024. She stated  
10 the Board of Pharmacy, in their legislation, must  
11 accredit the pharmacy schools, and they delegate that  
12 accreditation to ACPE.

13 Chair Roussel explained that ACPE has a very  
14 thick set of standards for evaluating colleges of  
15 pharmacy, and a member of the Board is requested to  
16 be present to oversee the process for on-site  
17 accreditation.]

18 MS. GETZEY HART:

19 I think we make a motion to send somebody  
20 and then they send schedules. We can  
21 determine who, after the fact, but just  
22 that we approve a member attending would  
23 be my recommendation.

24 MR. ESTERBROOK:

25 Second.

1 CHAIR ROUSSEL:

2 Any further discussion other than  
3 schedule this after the fact? All right.  
4 With that, call the vote.

5

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

9 [The motion carried unanimously.]

10

\*\*\*

11 Correspondence - FDA 13th Intergovernmental Working  
12 Meeting on Drug Compounding - March 18-19, 2025

13 [Christine Roussel, Pharm.D., BCOP, BCSCP,

14 Chairperson, noted the Food and Drug Administration's  
15 13th Intergovernmental Workgroup on Drug Compounding  
16 will be held March 18-19, 2025, and asked whether the  
17 Board wanted to send somebody from the Board of  
18 Pharmacy to attend the meeting focused on patient  
19 safety.]

20 MS. GETZEY HART:

21 I make a motion again, based on  
22 schedules, we send a representative and  
23 at that time also look at the proposed  
24 dates to determine if we may be able to  
25 work through that scheduling conflict if



1                   we can.

2 MR. ESTERBROOK:

3                   Second.

4 CHAIR ROUSSEL:

5                   Any discussion other than acknowledging  
6                   what a great suggestion is was to move  
7                   the date? All right. Let's call the  
8                   vote.

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 For the Board's Information - Public Inquiry  
16 [Sean C. Barrett, Esquire, Board Counsel, informed  
17 Board members that a licensee wanted to know how to  
18 propose a regulation change to allow pharmacy  
19 insurance to do transfers. He explained that a  
20 request like this is interesting because there is  
21 nothing one person can do to propose a regulation.  
22 He noted the Board writes the regulations and takes  
23 public comments, noting the public could bring  
24 something to the Board's attention even if it is not  
25 on the agenda.



1                   Roussel, aye.

2 [The motion carried unanimously.]

3   \*\*\*

4 [Christine Roussel, Pharm.D., BCOP, BCSCP,  
5 Chairperson, referred to § 27.26 regarding pharmacy  
6 interns, where an intern shall serve at least 500 of  
7 the 1500 hours in a pharmacy. She mentioned, through  
8 many discussions with the Board and the  
9 Pennsylvania Society of Health-System  
10 Pharmacists (PSHP), it was realized to be a barrier  
11 to pharmacy residents trying to come in from other  
12 states.

13           Chair Roussel explained that having someone come  
14 into the state, get a pharmacy preceptor, register as  
15 an intern, do the 500 hours, and then submit that to  
16 the Board delays licensure. She noted the Board did  
17 not want to affect out-of-state students' abilities  
18 to complete residencies in Pennsylvania. She  
19 mentioned it was waived in 2018, and the Board has  
20 renewed that waiver again that was retroactive at the  
21 beginning of the year.

22           Mr. Barrett informed the public that the Board  
23 would amend regulations to basically have this waiver  
24 incorporated, noting the regulatory process takes  
25 some time and is why there is a waiver.



1 effectuate the Pharmacy Act.

2 Mr. Farrell stated the Board's regulations are  
3 found at Title 49 of the Pennsylvania Code, which is  
4 where all regulations are found. He noted Title 49,  
5 in particular, is for the 29 boards and commissions  
6 that make up the BPOA within the Department of State.  
7 He also noted the State Board of Pharmacy regulations  
8 are at Chapter 27 of Title 49 and can be found  
9 online.

10 Mr. Farrell stated the Board reviews the  
11 regulations one piece at a time and solicits input  
12 from stakeholders concerning any revisions.

13 Mr. Farrell mentioned that the regulations being  
14 reviewed were first brought about in 2004 and issued  
15 as final in 2006. He referred to 16A-5427 regarding  
16 part II of the general revisions package. He  
17 mentioned existing topics already in the regulations  
18 and a few new sections that the Board may consider  
19 adding, including electronically transmitted  
20 prescriptions under § 27.201 and computerized  
21 recordkeeping systems under § 27.202.

22 Mr. Farrell noted splitting apart into one  
23 modified section and then a complementary new section  
24 dealing with centralized prescription processing on  
25 the first instance and centralized drug order

1 processing for the second part. He referred to  
2 automated medication systems under § 27.204 and as a  
3 new descriptor within a pharmacy or on the same  
4 premises as the pharmacy. He also referred to two  
5 brand new sections under § 27.205, remote automated  
6 medication systems, and § 27.206, emergency  
7 prescription drug availability and accessibility.

8 Mr. Farrell noted circulating a draft of the  
9 Board's last discussion regarding the regulations,  
10 which where were sent to all of the stakeholders. He  
11 also noted receiving one comment from the  
12 Pennsylvania Association of Chain Drugstores and the  
13 National Association of Chain Drugstores basically  
14 expressing support for the regulations, particularly  
15 the revisions to § 27.203-1 pertaining to centralized  
16 prescription processing.

17 Mr. Farrell stated comments were also received  
18 from the Pennsylvania Pharmacists Association that  
19 will be provided throughout the discussion.

20 Mr. Farrell referred to § 27.201 regarding  
21 electronically transmitted prescriptions and asked  
22 whether any changes were being done to that section.

23 Ms. Talbott noted the addition of the reference  
24 Controlled Substances Act (CSA) and Department of  
25 Health under Section 5. She also noted adding

1 "other requirements under federal or other state  
2 laws," so they would not have to go back and update  
3 it.

4 Jill Rebeck, Executive Director, Pennsylvania  
5 Society of Health-System Pharmacists, asked whether  
6 the proposed annex from July 26, 2024, is the version  
7 being discussed. Ms. Talbott noted the version to be  
8 July 26, 2024.

9 Mr. Farrell referred to § 27.202 but did not see  
10 any changes for computerized recordkeeping systems.

11 Larry Jones, Pennsylvania Society of Health-  
12 System Pharmacists, referred to (3) at the bottom of  
13 page 4, reporting if a pharmacist enters the  
14 prescription information but not as an intern or a  
15 tech does, noting it is addressed in later  
16 processing. He asked whether the phases could be  
17 added for a catch all.

18 Mr. Farrell stated it was one of PPA's comments,  
19 where everywhere they say pharmacy technician they  
20 should be saying "and pharmacy technician trainee"  
21 and "intern" on this one.

22 Acting Commissioner Claggett noted a comment  
23 online from Jacquelyn Sassaman referring to (a)  
24 asking whether they are including an attachment of a  
25 signed Rx via email for § 27.201.

1 Mr. Farrell explained that this would not be the  
2 last time the public has a chance to comment because  
3 it will be sent out as an exposure draft, goes to  
4 proposed and gets published in the *Pennsylvania*  
5 *Bulletin* for a 30-day public comment period.

6 Mr. Farrell answered a public comment asking how  
7 to be added to the stakeholder list and explained  
8 that they would need to send an email to the resource  
9 account or Mr. Barrett.

10 Mr. Farrell noted § 27.203-1 centralized  
11 prescription processing was created to distinguish it  
12 from § 27.203-2.

13 Rebecca Taylor, Pharm.D., Vice President,  
14 Pharmacy Services, University of Pittsburgh Medical  
15 Center, asked whether they could add checking an IV  
16 product using an IV workflow system with photos and  
17 gravimetrics under the definition of centralized  
18 prescription processing, so it would also be part of  
19 the definition of centralized prescription processing  
20 that they could leverage across the health system.

21 Ms. Talbott stated it was broken out separately  
22 for centralized prescription processing for  
23 centralized drug order processing.

24 Mr. Jones questioned the intent of § 27.203-1 and  
25 § 27.203-2 having identical first paragraphs.



1 Ms. Talbott stated it is for prescription versus  
2 drug order and outpatient versus inpatient. She  
3 noted it became very convoluted when they tried to  
4 put it together. She mentioned that they cannot call  
5 drug or a drug prescription and referred to Section  
6 1, where the definitions are prescription versus drug  
7 order.

8 Chair Roussel referred to prescription written,  
9 electronic, or oral order issued by a licensed  
10 medical practitioner in the course of professional  
11 practice or other drug device or medication. She  
12 noted being told that the intent was to separate  
13 institutional practice for the ability to have a  
14 different level of perspective on it than outpatient  
15 and is why they refer to it as order.

16 Chair Roussel noted similar language in the Model  
17 Practice Act to bifurcate the approach and mentioned  
18 that the ASHP Model Practice exists and is available  
19 for free.

20 Mr. Farrell noted PPA had a written comment for  
21 page 8 of the draft concerning (c)(2), where none of  
22 the databases duplicated, downloaded, or removed from  
23 the pharmacy's electronic database is the language,  
24 asking would a normal daily pharmacy backup in case a  
25 catastrophe be considered a duplicate and whether

1 they can strike the word "duplicated."

2 Ms. Talbott explained that it was lifted right  
3 from the tech statute and copied from the statute and  
4 did not believe they could change it. She suggested  
5 adding a sentence, "for the purpose of this section,  
6 duplication does not include backup of pharmacy  
7 records."

8 Acting Commissioner Claggett read a comment  
9 asking for the Board to repeat the directions for  
10 becoming a stakeholder.

11 Mr. Farrell asked Dr. Trimmer to put the Pharmacy  
12 Resource Account in the chat for anyone interested in  
13 becoming a stakeholder.

14 Mr. Jones referred to the definition of  
15 prescription versus medication order, that it is the  
16 reason the labeling requirements on page 6 are strict  
17 about following § 27.18, which is really outpatient.  
18 He noted Section 2 then follows the labeling  
19 requirements of § 27.18, so the clarification with  
20 outpatient versus inpatient helps to clarify the two  
21 sections.

22 Chair Roussel noted there is different labeling  
23 for institutional pharmacies. She mentioned looking  
24 into standardize language. She noted NABP has a  
25 chart order, so a lawful order on a chart or medical

1 record of an inpatient or a residential or a resident  
2 of an institutional facility, and it has a little bit  
3 different instructions around it versus the  
4 definition of a prescription drug which is broad and  
5 then a prescription drug order. She mentioned that  
6 she wanted to read a little bit more before  
7 suggesting to change it.

8 Mr. Farrell referred to § 27.203-2 regarding  
9 centralized drug order processing. He noted PPA had  
10 the same comment on this one regarding the duplicate  
11 issue and could address it the same way.

12 Chair Roussel referred to § 27.203-2, when  
13 filling a prescription, compounding is filling, and  
14 could be added in the first definition because it is  
15 just another way to fill a prescription. She noted  
16 the United States Pharmacopeia (USP) does not address  
17 that, where for sterile compounding and even USP 795,  
18 it is really more technical and facility-wise, and  
19 there is no statement about who should use  
20 automation.

21 Chair Roussel commented that the benefit of  
22 automation cannot be understated for remote  
23 verification and referred to the insight that was  
24 provided by the one hospital that said part of their  
25 mitigation plan was that they will be taking scanning

1 and barcode pictures of when they are compounding.  
2 She noted the technology is already in place but  
3 asked whether to add it to the language or whether it  
4 is understood.

5 Chair Roussel asked whether the Board members  
6 were agreeable with the definition to fill or refill  
7 a drug includes to compound it, so it does give the  
8 ability for that where there would be remote  
9 verification of compounding. She mentioned there  
10 were many questions as to whether they are in the  
11 building or in another building. This allows for  
12 centralized drug order processing.

13 Chair Roussel asked whether and where that should  
14 be added. She believed people are already doing  
15 this, and it has already legally been assumed under  
16 the way it is written about filling it and believed  
17 it to be already a part of their state law and  
18 legally acceptable.

19 Brett Rodgers, Senior Manager for Pharmacy  
20 Automation, University of Pittsburgh Medical Center,  
21 referred to process fill, or refill, noting one could  
22 argue that filling is the same, where compounding is  
23 different because they are still preparing one way or  
24 the other and believed that part is defined  
25 perfectly. He mentioned that the piece where it

1 starts to get a little bit questionable is when they  
2 reach the automated medication systems in § 27.204.

3 Dr. Taylor referred to DEA Labeling, where it  
4 clearly shows the name, address, phone number, if  
5 applicable, the DEA, number of the requesting  
6 pharmacy or the delivery pharmacy or both. She  
7 believed it should come from the place that is  
8 dispensing the drug, not necessarily the place that  
9 is verifying the order.

10 Dr. Taylor mentioned that UPMC Northwest is  
11 closed overnight, and if they had to label an order  
12 for a patient, it would be labeled by the pharmacy  
13 dispensing the drug with the DEA number. She stated  
14 it is confusing where it says requesting pharmacy,  
15 delivering pharmacy, or both because it should really  
16 come from where it is being dispensed.

17 Ms. Talbott stated they could strike the "or  
18 both" because because they have either requesting or  
19 the delivery. There are other states that require  
20 both or one or not the other, and that is why they  
21 put both in there.

22 Mr. Rodgers noted the punchline is traceability.  
23 If there is a question of where that came from,  
24 providing the DEA and the pharmacy verify that it is  
25 not a dispensing pharmacy, so they have to trace that

1 back to know where it came from.

2 Mr. Rodgers addressed somebody who does not have  
3 access to the other facility's automation, such as  
4 somebody at Magee would not have access to Presby's  
5 automation, so in terms of a hospital order, where  
6 they are filling for multiple facilities, does that  
7 matter.

8 Chair Roussel stated, if they took that bullet  
9 out, it would give the opportunity for people to  
10 customize based on what they are doing, as there  
11 could be an infinite number of scenarios. She  
12 mentioned being in a multihospital health system and  
13 something happens in one location and there is a  
14 serious problem, somebody else would have to step in.  
15 So there are emergency considerations as well. She  
16 noted it may be better not including it and allow the  
17 organization to determine the flow.

18 Ms. Talbott noted the need for that automation  
19 trail. The pharmacies engaged in centralized drug  
20 order processing have to have a common electronic  
21 file or use other secure means that permit the  
22 central pharmacy to access and recover the required  
23 information.

24 Ms. Talbott noted they could remove (a)(2)(ii) at  
25 the top of page 10 but would still have to have some

1 way to access the whole system and have the auto  
2 trail.

3 Chair Roussel asked whether another hospital  
4 providing sterile compounding services or sending  
5 patient-specific prescriptions would need to pull up  
6 the automation that shows the lot number of the vial  
7 at the other facility. She noted it would be nice  
8 but what is the need to do that, where they could do  
9 it if they were hopping through a system.

10 Mr. Rodgers expressed concern with whether a  
11 staff pharmacist would go back if there is a problem  
12 and log into that other hospital's system, where they  
13 are basically saying everybody in their health system  
14 have to be able to access across multiple servers.

15 Mr. Rodgers reported having 40 different  
16 automation services at UPMC and breaking that up  
17 depending on who is dispensing what and saying Presby  
18 could cover for this subset of places. Everybody  
19 needs access to that to be able to provide that trail  
20 but would every single staff pharmacist at a large  
21 location be able to go across.

22 Mr. Jones noted CHS Corporate had 136 hospitals,  
23 and their first three prescription numbers identified  
24 the hospital, and the rest of the numbers were  
25 numeric to their pharmacist, where the first four

1 numbers could identify the source.

2 Mr. Jones mentioned that CVS and Weiss do the  
3 same thing by having store numbers for the first four  
4 digits. He mentioned that it may not be the  
5 prescription number itself but identify using it as a  
6 secondary label line that identifies the store  
7 number. He reported doing it as part of the  
8 prescription number in their labels and making the  
9 prescription number 13 digits for the automation  
10 trail.

11 Ms. Talbott referred to bullet 5, each pharmacy  
12 engaging in central orders, like processing, shall  
13 jointly be responsible for and then bullet 5 is  
14 providing for inspection, any required records or  
15 information within 72 hours of the request by the  
16 Board. She noted (3) would allow an automation trail  
17 and bullet 5 says 72 hours for an inspector.

18 Ms. Talbott mentioned that what may be clinically  
19 relevant at that moment for that nurse may not  
20 necessarily take 72 hours but is that already  
21 connected in a way that it is acceptable. She noted  
22 HER is the same through all the hospitals, but  
23 different hospitals may have different compounding  
24 systems and its own set of logs and papers for what  
25 is actually there.



1 Ms. Talbott commented that it may not make sense  
2 for people to have access to compounding systems in  
3 another institution. She mentioned that she did not  
4 read it as inappropriate but could open it back up  
5 for additional discussion in January.

6 Ms. Talbott recommended everyone look at the NABP  
7 Model Practice Act and highlighted that NABP has a  
8 committee looking at institutional compounding  
9 regulations.

10 Dr. Taylor referred to legal requirements on page  
11 9 under § 27.203-2 after § 27.18 regarding labeling  
12 requirements, unless the medication is removed from  
13 an automated dispensing cabinet. It would be  
14 complicated to ensure that Always Better Control  
15 (ABC) has the name of the patient; ingredients; the  
16 name, strength, and quantity; dilutant; exploration  
17 date; and initials of a pharmacist that goes directly  
18 to a nurse.

19 Dr. Taylor asked whether they could consider the  
20 patient's name and another patient identifier  
21 approved by the institution, whether it is the  
22 medical record number (MRN), date of birth, etc.,  
23 because they would not be able to do that and cannot  
24 comply with § 27.18 unless they have a carve out for  
25 coming out of an ABC on page 9.

1 Dr. Taylor referred to § 27.18(2)(b) that lists  
2 the drug order institutional labeling requirements.  
3 She noted not being sure whether many hospital  
4 systems were currently compliant with that  
5 regulation, because a pharmacist is not checking it  
6 before it gets removed, and if the nurse is putting a  
7 min-bag or a vial together, they are not checking it.

8 Ms. Talbott referred to § 27.203-2 at the bottom  
9 of the page, the container and then after § 27.18,  
10 unless removed from automated dispensing cabinet.

11 Dr. Taylor felt strongly about having two patient  
12 identifiers, even if the nurse pulls it out, noting  
13 most hospitals would have a policy about a patient  
14 name and a patient identifier, but it does not have  
15 all the elements of § 27.18.

16 Mr. Jones referred to labeling for hospitals  
17 section, noting there are details in the actual  
18 chapter about a nurse handling a unit dose or a unit  
19 of issued medications, and anything outside of that  
20 has to be labeled.

21 Dr. Taylor noted that when a nurse pulls the  
22 components in an emergent situation and makes a  
23 norepinephrine badge that it is not labeled.

24 Chair Roussel read § 27.18(b), where as long as  
25 the drug is dispensed in a unit dose that it does not

1 require the labels. She noted someone making an on-  
2 demand IV that it is an example of a unit dose.

3 Chair Roussel noted that it is allowing central  
4 drug order processing and their question is, as it  
5 relates to automated dispensing cabinets, do they  
6 allow a pharmacist to remote into another site and  
7 verify an order, which we already do now. She  
8 believed they are extrapolating to another and was  
9 not sure if that was needed.

10 Ms. Talbott noted the section is just central  
11 fill and they are patient-specific, which is 204,  
12 206.

13 Chair Roussel noted that she could see why they  
14 want to add the container is labeled appropriately  
15 unless removed from an automated dispensing cabinet.  
16 If they do that and get rid of (ii), then they refer  
17 to labeling for automated dispensing cabinets, which  
18 they do not have. She liked the idea of striking  
19 (ii), and then at the bottom of page 9 after §  
20 27.18(b) adding "unless removed from an automated  
21 dispensing cabinet." She also believed it should be  
22 removed from an "automated medication system" because  
23 that is the term being used.

24 Chair Roussel asked whether any other changes  
25 needed to be made to § 27.203-2. She noted they had

1 questions about the audit, but then felt good that  
2 even though it says audit, they had (v) on page 11  
3 that says they have 72 hours.

4 Ms. Talbott noted that is pretty standard across  
5 the regulations on providing information to the Board  
6 within 72 hours and cautioned making that a different  
7 timeline to keep it uniform. She mentioned if they  
8 would put the caveat in § 27.203-1 about none of the  
9 database is duplicated, put the caveat that backups  
10 are not a duplication in both sections, § 27.203-1 and  
11 § 27.203-2.

12 Mr. Farrell referred to § 27.204, automated  
13 medication systems within a pharmacy or on the same  
14 premises as the pharmacy.

15 Ms. Talbott noted they split this out into two,  
16 and they read similarly.

17 Dr. Taylor agreed that it needs to be clear,  
18 central pharmacy automation versus on-site.

19 Chair Roussel wanted to start with the  
20 definition, for the purposes of this section,  
21 automated medication systems means the process that  
22 performs operations or activities and it says other  
23 than compounding or administration. She wanted to  
24 strike compounding from that, because they use an  
25 amazing number of robots that do compounding. She

1 wanted to remove the line that says other than  
2 compounding or administration.

3 Mr. Farrell referred to the definition section in  
4 § 27.1, noting automated medication system was the  
5 exact same wording.

6 Ms. Talbott noted to also strike it in the  
7 definition in that section.

8 Ms. Talbott noted a comment regarding automated  
9 counting devices, where inspectors are calling out  
10 counting machines in a pharmacy, like automated  
11 dispensers, and questioning if it has all the bells  
12 and whistles in the current regulations. She stated  
13 they were clear to put it in that it does not include  
14 a machine that sits on the counter that you pour the  
15 medication in and it spits out 30. She mentioned  
16 that it may be something to follow up with the  
17 inspectors.

18 Mr. Farrell mentioned that the commenter felt the  
19 Board and inspectors view the Yuyama and Parata  
20 devices as automated medication systems and not as  
21 counting machines, which the commenter did not  
22 believe was the intent of the initial regulation. He  
23 noted the commenter proposes a definition be added to  
24 the regulations for automated counting machine or  
25 clarifying what "all transaction history" includes.

1 Ms. Talbott explained that they determined it  
2 does not include an automatic counting device, like a  
3 Parata or unit-based dispensing cabinet. She noted  
4 that what is in the regulations now was meant to take  
5 care of situations where a pharmacy has a machine at  
6 the nursing home, not so much automated, which is why  
7 they broke it out.

8 Dr. Taylor asked where a retail-based Parata  
9 automated centralized pharmacy medication system is  
10 in their rules and regulations.

11 Ms. Talbott noted it is just a tool.

12 Mr. Jones noted being stuck on administration  
13 because all administration as an inpatient is under  
14 the Department of Health regulations, and they have  
15 to adhere to that, so all of the pharmacy automated  
16 medication systems have to do with storing inventory  
17 and dispensing but not administration. He mentioned  
18 that leaving in administration or putting the caveat  
19 that says to follow the Department of Health  
20 regulation, even if it goes to robotics, the  
21 Department of Health (DOH) would have to approve  
22 that.

23 Chair Roussel did not believe they have to say  
24 not including administration. She noted the word  
25 "compounding" could be added down below to be more

1 prescriptive and then not lift administration.

2 Mr. Farrell confirmed inserting compounding in  
3 the third line between packaging and dispensing and  
4 striking other than compounding or administration.  
5 He noted the same would be done in the definition  
6 section in § 27.1.

7 Mr. Farrell noted a comment for § 27.204(a)  
8 asking for the definition of a unit-based dispensing  
9 cabinet.

10 Dr. Taylor stated it needed to be the same as  
11 § 27.205.

12 Mr. Farrell referred to a comment asking what the  
13 purpose is of adding statistically at the top of page  
14 13 at (b) (2) and how it would be monitored or  
15 measured, what are the statistics, and whether there  
16 would be a policy on how to validate the accuracy of  
17 the system.

18 Ms. Talbott noted the information came from NABP.

19 Mr. Jones noted the same could be applied for  
20 number (3), whereby the Board may independently  
21 validate the accuracy.

22 Dr. Taylor suggested recommending language in  
23 (b) (2), the automated medication system has been  
24 tested and validated as per pharmacy policy or  
25 something to that effect if there is the need for

1 some type of validation. She noted that  
2 statistically, across at least 30 different health  
3 systems, everyone had a question of what that means.  
4 She suggested saying validated to vendor specs.

5 Ms. Talbott noted independently would be left in  
6 if statistically was taken out because of the need to  
7 be able to validate how their machine counts 100 of  
8 furosemide.

9 Dr. Taylor stated the machines can only be as  
10 accurate as the vendor specs, but assuming she  
11 applied all the vendors specs and someone comes in  
12 and independently validates it, she believed it  
13 should say it was according to the vendor published  
14 specifications of the technology.

15 Ms. Talbott commented that someone will not  
16 implement it if it is not accurate and getting the  
17 wrong amount four out of five times is a problem.

18 Chair Roussel believed the Board should retain  
19 the right and suggested cutting statistically in (2)  
20 and leave independently in (3).

21 Mr. Farrell referred to a comment, where the  
22 commenter pointed out that if they would say pharmacy  
23 technician that they should say trainee as well.

24 It was noted the last sentence has a typo and  
25 should read, the pharmacist will be held responsible



1 for transactions performed by the pharmacy intern or  
2 tech.

3 Dr. Taylor noted not understanding the purpose of  
4 who are designated in writing by the pharmacist  
5 overseeing the system because it could be so many  
6 different employees and should be anyone under the  
7 supervision of a pharmacist.

8 Ms. Talbott noted it would be in the technician  
9 protocol.

10 Mr. Farrell confirmed removing in writing and  
11 have it read, are designated by the pharmacist in  
12 charge.

13 Mr. Farrell referred to a comment concerning  
14 § 27.204 in the middle of page 15, where billing staff  
15 manager/admin may need access to records.

16 Ms. Talbott suggested it read, identified  
17 individuals who have access to records of medication  
18 and other medical information.

19 Ms. Taylor referred (3) on page 15, set forth  
20 methods that ensure retention of each amendment;  
21 addition, deletion, or other change to the policies  
22 and procedure. She noted policies and procedures are  
23 often electronic and asked how they would comply with  
24 signed or initials by the pharmacist in charge.

25 Ms. Talbott explained that they do not say it

1 cannot be electronic.

2 Mr. Farrell referred to a comment for § 27.204 at  
3 the top of page 16, where the machine is on the  
4 pharmacy premises, what medical practitioners would  
5 have access to machines on a medical practitioner  
6 site. He noted there was concern about medical  
7 practitioner access as well.

8 Dr. Taylor noted it to be anyone appropriate  
9 within their medical field.

10 Mr. Farrell confirmed no change would be needed.

11 Mr. Farrell referred to a comment for § 27.204 at  
12 the top of page 17, where the language requires  
13 monitoring of the automated medication system. He  
14 noted the commenter asked what constitutes monitoring  
15 and whether this could be monitored remotely and by  
16 exception.

17 Ms. Talbott noted that it does not say it cannot.

18 Mr. Farrell noted § 27.204 would read identified  
19 individuals who may access records of medications and  
20 other medical information of the patient maintained  
21 by the pharmacy.

22 Mr. Farrell referred to § 27.205 and commented  
23 that a provider pharmacy means that a pharmacy  
24 provides services to a long-term care facility under  
25 a written contract and believed it should be to other

1 locations because there are clinics and other  
2 scenarios.

3 Ms. Talbott noted she highlighted other locations  
4 and suggested changing all those to other locations  
5 but striking (b)(1).

6 Chair Roussel noted, when referring to the  
7 language before that, the automated medication system  
8 definition would need corrected to remove the  
9 compounding or administration and then relative to  
10 the storage, administration, dispensing, etc.

11 Mr. Farrell referred to comments on page 20  
12 concerning § 27.205(d), asking whether other  
13 authorized personnel could be authorized personnel of  
14 the pharmacist or long-term care facility or both.

15 Ms. Talbott explained that it is covered in (g)  
16 in policies and procedures.

17 Mr. Farrell referred to a comment noting Section  
18 3 specifies long-term care facility personnel,  
19 whereas 4(d) does not and would like to see it state  
20 other pharmacy or long-term care facility personnel.

21 Dr. Taylor believed for clarification and  
22 referred to § 27.205(a)(1), where they are changing  
23 long-term care facility to other locations, except  
24 that they are striking § 27.205(b)(1).

25 Mr. Farrell referred to the next comment

1 concerning (d) (2) asking for the definition of  
2 container, whether it is in the packaging that the  
3 medication is in or the drawer that contains multiple  
4 containers or drugs. If it is the container, then  
5 would everything be considered removable and asked  
6 why the word removable was needed.

7 Mr. Farrell confirmed removing (d) (2).

8 A question was referred to concerning (d) (3),  
9 automated medication system uses barcode verification  
10 and noted barcode verification is not defined  
11 anywhere and is the basis for all of the remote  
12 verification that would be used everywhere, and a  
13 definition was needed.

14 Mr. Barrett noted it is also saying barcode  
15 verification, electronic verification, or similar  
16 process and is not just limited to barcode  
17 verification. He noted a definition could be added  
18 but expanding the other items kind of expands the  
19 universe of different verifications.

20 Ms. Talbott suggested saying, automated system  
21 uses a process, such as, to assure the container.

22 Mr. Farrell confirmed the Board liked the way it  
23 is worded.

24 Mr. Farrell referred to page 21 Section (f),  
25 where the commenter suggested allowing a certified

1 pharmacy technician to conduct the monthly  
2 inspection.

3 Dr. Taylor agreed for it to read, a pharmacist or  
4 designee did not necessarily need to be on-site for  
5 inspections.

6 Chair Roussel mentioned having a long discussion  
7 and to have on-site remain but designee sounds good.

8 Mr. Jones noted monthly inspections are required  
9 for all off-site facilities because they are  
10 considered a department of the hospital and licensed  
11 by the DOH in that format no matter how they do the  
12 billing and is why the monthly inspection on-site is  
13 required. He stated the monthly inspection can  
14 consist of expired removals. Board members agreed to  
15 change it to pharmacist or designee.

16 Mr. Farrell referred to page 22 subsection (4),  
17 noting it may have already be taken care of from the  
18 long-term care to other locations. He noted the  
19 commenter stated this section does not make sense,  
20 deny/grant access to whom, a particular LTC staff  
21 pulling the drug, a particular LTC patient, or  
22 whether they granting/denying that a particular drug  
23 can go in the machine.

24 Dr. Rogers read that as access to the system,  
25 including the ability to log in and perform

1 functions. He noted it is not always the pharmacist  
2 generating access and doing it at the direction of  
3 the manager or supervisor.

4 Mr. Farrell noted the addition of "or a  
5 designee."

6 Mr. Farrell referred to § 27.206, remote  
7 automated medication systems. He noted a comment  
8 asking whether they could have multiple supervisors  
9 of the kit and suggested supervising pharmacists.

10 Ms. Talbott stated they did not put the  
11 pharmacist in charge because they wanted it to be  
12 somebody who had ownership of that emergency kit at  
13 the site.

14 Chair Roussel noted the contents of the trays are  
15 reviewed by a committee and who has access to that  
16 emergency kit and then the people who replenish it,  
17 but a pharmacist is checking it. She stated a  
18 pharmacist should be checking an emergency kit before  
19 it leaves the pharmacy.

20 Ms. Talbott noted provider pharmacy means a  
21 pharmacy that provides services. This was a box at  
22 the long-term care, not the emergency kit. She noted  
23 the items are sometimes in a toolbox, sometimes in a  
24 tackle box, but they have to be locked. Board  
25 members agreed § 27.206 was not needed.

1           Mr. Esterbrook stated the DEA has separate  
2 regulations on an emergency kit versus an automatic  
3 dispensing unit at a long-term care facility and that  
4 may be why this is separate. He noted an emergency  
5 kit does not have to be registered with the DEA but  
6 it does if it is a dispensing cabinet.

7           Mr. Esterbrook also noted being able in a nursing  
8 home to get a tramadol out specific to a patient  
9 order, but an emergency kit is delivering the  
10 tramadol at 5 p.m. If it is needed at noon, the one  
11 dose can be taken out. He explained that the DEA has  
12 two separate sets of regulations, and that may be why  
13 there is specific wording for an emergency kit.

14           Chair Roussel believed their plan is to conduct  
15 another regulatory work session on January 21, 2025,  
16 and suggested everyone perform independent research  
17 and vote later about whether or not to delete § 27.206

18           Mr. Farrell noted the Board discussed § 27.21 to  
19 § 27.27 in December but needed to look into whether  
20 the first part was completely finished as far as the  
21 Board.

22           Ms. Talbott noted they did not make any edits  
23 related to the pharmacist section regarding licensing  
24 but did make changes to § 27.11 regarding the waiver  
25 to use another designation and intern piece.

1           Chair Roussel noted the need to revisit that  
2 whole entire section because of UPJE. She referred  
3 to § 27.21, application for examination and licensure,  
4 where a candidate for pharmacy practice shall take  
5 the North American Pharmacist Licensure Exam (NAPLEX)  
6 and the Multistate Pharmacy Jurisprudence Exam and  
7 shall obtain an application for licensure.

8           Chair Roussel noted wanting to use broader  
9 language saying, a Pharmacy Jurisprudence Exam and  
10 not specify which state. She mentioned that the law  
11 gives them the ability to change it in the  
12 regulations, and they should. She noted she wanted  
13 to allow students to take the law exam prior to  
14 graduation. She commented that they are the only  
15 healthcare profession that makes people take two  
16 exams, and it is a little overwhelming for the  
17 students to have to take two licensing exams.

18           Mr. Jones questioned how many other sections  
19 would be reviewed as far as the second round.

20           Chair Roussel offered to work with Mr. Farrell to  
21 line up what was reviewed the last time and this  
22 time.

23           Mr. Farrell explained that a game plan for how it  
24 would all piece together had not yet been confirmed.  
25 He believed the Board could commit to putting it all



1 together rather than making a third part.

2 Mr. Barrett reminded everyone to discuss changes  
3 in open session.

4 Chair Roussel explained that the Board needed to  
5 review what had not yet been discussed and set dates  
6 for it to be prepared.

7 Dr. Taylor requested clarification that the  
8 session in January 2025 would include a regulatory  
9 work session that included the associated content and  
10 possibly licensure.

11 Chair Roussel stated the goal for December would  
12 be to cover that whole stretch. She noted that  
13 December is the American Society of Health-Systems  
14 Pharmacists Meeting and suggested January instead,  
15 because they would be missing a third of the  
16 stakeholders.

17 Mr. Farrell offered to provide updates in January  
18 of the section of the regulations discussed except  
19 for § 27.206.]

20 \*\*\*

21 Adjournment

22 CHAIR ROUSSEL:

23 I entertain a motion to end the meeting

24 MR. ESTERBROOK:

25 Motion to close.

1 MS. GETZEY HART:

2 Second.

3 \*\*\*

4 [There being no further business, the State Board of  
5 Pharmacy Meeting adjourned at 12:54 p.m.]

6 \*\*\*

7

8 CERTIFICATE

9

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

15

16

17



18

Samantha Bruer,

19

Minute Clerk

20

Sargent's Court Reporting

21

Service, Inc.

22

23

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25

26

STATE BOARD OF PHARMACY  
REFERENCE INDEX

October 22, 2024

	TIME	AGENDA
1		
2		
3		
4		
5		
6		
7		
8		
9	9:00	Executive Session
10	10:30	Return to Open Session
11		
12	10:30	Official Call to Order
13		
14	10:30	Introduction of Board Members/Attendees
15		
16	10:35	Approval of the Agenda
17		
18	10:36	Approval of Minutes
19		
20	10:37	Report of Board Prosecution
21		
22	11:01	Report of Board Counsel
23		
24	11:02	Report of Board Chairperson
25		
26	11:10	Report of Acting Commissioner
27		
28	11:11	Report of Executive Secretary
29		
30	11:12	Review of Applications
31		
32	11:12	Correspondence
33		
34	11:15	For the Board's Information
35		
36	11:17	Old Business
37		
38	11:24	Report of Board Counsel (cont.)
39		
40	12:54	Adjournment
41		
42		
43		
44		
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