State Board of Pharmacy November 7, 2023

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BOARD MEMBERS:

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

BUREAU PERSONNEL:

Carole Clarke Smith, Esquire, Senior Board Counsel Ariel O'Malley, Esquire, Board Counsel Ray J. Michalowski, Esquire, Senior Board Prosecutor Nathan C. Giunta, Esquire, Board Prosecution Liaison Glenn P. Masser, Esquire, Board Prosecutor Ashley P. Murphy, Esquire, Board Prosecutor Melanie Zimmerman, R.Ph., Board Administrator Marc Farrell, Esquire, Regulatory Counsel, Office of Chief Counsel, Department of State Jessica Zukoski, Senior Legal Analyst, Department of State

ALSO PRESENT:

Heather A. Wilson, MSW, CFRE, CAE, Executive Director, Foundation of the Pennsylvania Medical Society Physician's Health Program Tiffany Booher, MA, CADC, CIP, CCSM, Director, Peer Assistance Monitoring Programs, Foundation of the Pennsylvania Medical Society Peter Hlavinka, Pharmacy Director, St. Luke's University Health Network Matthew Mauro, Director of Pharmacy, Allentown Campus, St Luke's University Health Network Larry Jones, Executive Director, Pennsylvania Society of Health-System Pharmacists Jim Reed, Health Outcomes Supervisor/Strategic Partnerships Leader, Walgreens

$\frac{\text{State Board of Pharmacy}}{\text{November 7, 2023}}$

ALSO PRESENT: (cont.)

Michael Brinton, Stude
Pharmacy

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Michael Brinton, Student, Philadelphia College of Pharmacy

Abraham Gutman, Health Reporter, The Philadelphia Inquirer

Andrew Kuzy

Alison Apple, R.Ph., MS, Chief Pharmacy Officer, Hospital of the University of Pennsylvania

B. Johnson
Timothy Black, R.Ph., Pharmacy Inspector, Bureau of
Enforcement and Investigation, Department of State

Charlotte Harris, Pharmacy Intern, Duquesne University Sarah Everingham, MJ, CCEP, CPhT, Cardinal Health

Joshua Finger, Pharm.D., Enclara Pharmacia

Frank Konzelman Jr., PharmD, BCPS, Director of Pharmacy Services, Pennsylvania Pharmacists Association

Jacquelyn Sassaman, Pentec Health

24 Jennifer Kline

Jennifer Raibley, Division Pharmacy Manager, ACME Markets

27 Julie

David Klinger, System Director, Operations & Compliance, Geisinger Health System

Judy Kutchman, R.Ph., AllianceRx Walgreens Prime

Kerry E. Maloney, Esquire, Post & Schell, P.C. Matthew Roesch, R.Ph., Pharmacist-in-Charge,

Vetsource Pharmacy

Michael Porr, Immunizing Student Pharmacist, Giant Company

Christopher Miller, PharmD, Giant Eagle

Joseph Millward, Senior Manager, Pharmacy Quality and Accreditation, PANTHERx Rare Pharmacy

Nicole Fidler, Associate, Malady & Wooten

Patrick Lavella, R.Ph., President, Pennsylvania Pharmacist Association

Misha Patel, M.D., Curriculum Education Assistant, Geisinger Commonwealth School of Medicine

Valerie Pentland, PharmD, ConnectiveRx

Rhonda Thomas, PharmD, MBA, BSPS, BCSCP, Director of Pharmacy, Lehigh Valley Health Network

Kristofer Rivers, Clinical Supervisor, UPMC Pinnacle Laura Romeo, Pharmacist-in-Charge at ConnectiveRx,

49 | Careform Pharmacy 50 |

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ALSO PRESENT: (cont.)

Grace Sesi, Executive Director, Regulatory Affairs at CVS Health/Chairperson, Michigan Board of Pharmacy Steven Zahn, Pharmacy Inspector, Bureau of

Enforcement and Investigation, Department of State Geoffrey Christ, Senior Pharmacy Compliance Manager, Chewy

Edward Foote, Pharm.D., FCCP, BCPS, Dean, Philadelphia College of Pharmacy at the University of Sciences

Maimuna Bruce, PharmD, MBA, MS, Pharmacy Advocacy/ Regulatory Affairs Manager

Karen Kozachyn, EdD, Vice President, Delaware County Community College

John Stevenson

Lisa Jones

23 Diane 24 Devin

Devin Nunemaker

25 Thomas Fortunato 26

Sargent's Court Reporting Service, Inc. (814) 536-8908

5 * * * 1 2 State Board of Pharmacy 3 November 7, 2023 * * * 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 Ariel E. O'Malley, Esquire, Board Counsel, for the purpose of conducting quasi-judicial deliberations and to receive the advice of Board 10 Counsel. The Board returned to open session at 10:30 a.m.] 11 * * * 12 13 The regularly scheduled meeting of the State 14 Board of Pharmacy was held on Tuesday, November 7, 15 2023. Theresa M. Talbott, R.Ph., Chairperson, called 16 the meeting to order at 10:34 a.m. * * * 17 18 Pledge of Allegiance 19 [The Pledge of Allegiance was recited.] * * * 20 21 [Theresa M. Talbott, R.Ph., Chairperson, noted that 22 the meeting was being recorded, and those who 23 continued to participate were giving their consent to 24 be recorded. 1 25

6 Evacuation Announcement 1 2 [Melanie Zimmerman, R.Ph., Board Administrator, 3 reviewed the emergency evacuation procedures for One 4 Penn Center.] 5 * * * Introduction of the Board Members/Audience 6 7 [Theresa M. Talbott, R.Ph., Chairperson, requested an introduction of Board members, Board staff and the 9 audience.1 10 11 Approval of the Agenda CHAIRPERSON TALBOTT: 12 13 I'll accept a motion to approve the 14 agenda, noting our appointment at 15 10:50 a.m. has canceled, and we are 16 removing item 31. 17 Eric, would you like to make that 18 motion? MR. ESTERBROOK: 19 20 So moved. 21 MS. GETZEY HART: 22 Second. 23 CHAIRPERSON TALBOTT: 24 Any other discussion? Call the vote. 25

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                 Esterbrook, aye; Hart, aye; Claggett,
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                 aye; Talbott, aye; Roussel, aye; Ritchie,
3
                 aye; Slagle, aye.
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   [The motion carried unanimously. Item 31 was CVS
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   Pharmacy 5726.]
                              * * *
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   Approval of Minutes
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   CHAIRPERSON TALBOTT:
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                 At number 3, we have the minutes from
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                 August 29. Did anybody find any
                 corrections to the minutes?
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   MR. ESTERBROOK:
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                 Motion to accept the minutes.
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   CHAIRPERSON TALBOTT:
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                 Second?
   MS. GETZEY HART:
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                 Second.
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   CHAIRPERSON TALBOTT:
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                 Any discussion? Call the vote.
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21
                 Esterbrook, aye; Hart, aye; Claggett,
22
                 abstain; Talbott, aye; Roussel, aye;
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                 Ritchie, abstain; Slagle, aye.
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   [The motion carried. Arion Claggett and Tyler
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   Ritchie abstained from voting on the motion.]
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8 1 2 Report of Board Prosecution 3 [Glenn P. Masser, Esquire, Board Prosecutor, 4 presented the Consent Agreements for Case Nos. 22-54-5 007663 & 21-54-017899, Case No. 23-54-006378, Case No. 22-54-002123, Case Nos. 21-54-004050 & 22-54-6 7 008273, and Case No. 22-54-013715. 8 9 [Theresa M. Talbott, R.Ph., Chairperson, exited the 10 meeting at 10:47 a.m. for recusal purposes.] * * * 11 VICE CHAIR ROUSSEL ASSUMED THE CHAIR 12 13 * * * 14 [Glenn P. Masser, Esquire, Board Prosecutor, 15 presented the Consent Agreement for Case Nos. 21-54-16 014114 & 21-54-019176.1 17 18 [Nathan C. Giunta, Esquire, Board Prosecution 19 Liaison, presented the Consent Agreement for Case No. 20 22-54-012329.1 * * * 21 22 [Theresa M. Talbott, R.Ph., Chairperson, reentered 23 the meeting at 10:49 a.m.] 24 25 CHAIRPERSON TALBOTT RESUMED THE CHAIR

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2 [Ashley P. Murphy, Esquire, Board Prosecutor,

3 presented the Consent Agreement for Case No. 23-54-

4 004066.1

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6 | [Nathan C. Giunta, Esquire, Board Prosecutor,

7 presented the Consent Agreements for Case No. 22-54-

8 018675 and Case No. 20-54-008051.]

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10 | [Ray J. Michalowski, Esquire, Senior Board

11 Prosecutor, presented the VRP Agreement Case No. 23-

12 54-012206 and Case No. 22-54-002561.]

13 CHAIRPERSON TALBOTT:

14 The Board of Pharmacy met in Executive

Session to consider Consent Agreements

before the Board.

Do we have any motions on those?

18 MR. ESTERBROOK:

19 I move to accept the Consent Agreement at

20 Case Nos. 22-54-007663 & 21-54-017899.

21 CHAIRPERSON TALBOTT:

22 We have a motion. Do we have a second?

23 MS. GETZEY HART:

24 Second.

25 CHAIRPERSON TALBOTT:

10 1 Any discussion? Call the vote. 2 3 Esterbrook, aye; Hart, aye; Claggett, aye; Talbott, aye; Roussel, aye; Ritchie, 4 5 aye; Slagle, aye. [The motion carried unanimously. The Respondents' 6 7 names are Daniel Tang and Tang Pharmacy, Inc., 8 t/d/b/a Tang Pharmacy.] 9 10 MR. ESTERBROOK: 11 I move to accept the Consent Agreement at Case No. 23-54-006378. 12 13 CHAIRPERSON TALBOTT: We have a motion. Do we have a second? 14 15 MS. GETZEY HART: 16 Second. CHAIRPERSON TALBOTT: 17 18 Any discussion? Call the vote. 19 20 Esterbrook, aye; Hart, aye; Claggett, 21 aye; Talbott, aye; Roussel, aye; Ritchie, 22 aye; Slagle, aye. 23 [The motion carried unanimously. The Respondent's 24 name is Edwin Allen Jr., R.Ph.] * * * 25

12 [The motion carried unanimously. The Respondent's 1 2 name is PostMeds, Inc.] 3 4 MR. ESTERBROOK: 5 I move to accept the Consent Agreement at Case Nos. 21-54-014114 & 21-54-019176. 6 7 MS. GETZEY HART: 8 Second. 9 CHAIRPERSON TALBOTT: 10 Any discussion? Call the vote. 11 12 Esterbrook, aye; Hart, aye; Claggett, 13 aye; Talbott, recuse; Roussel, aye; 14 Ritchie, aye; Slagle, aye. 15 [The motion carried. Theresa Talbott recused herself 16 from deliberations and voting on the motion. 17 Respondents' names are CVS Pharmacy 4013 & Brandon M. 18 Schwartz, R.Ph.] * * * 19 MR. ESTERBROOK: 20 21 I move to accept the Consent Agreement at 22 Case No. 22-54-013715. 23 MS. GETZEY HART: 24 Second. 25 CHAIRPERSON TALBOTT:

13 1 Any discussion? Call the vote. 2 3 Esterbrook, aye; Hart, aye; Claggett, 4 aye; Talbott, aye; Roussel, aye; Ritchie, 5 aye; Slagle, aye. 6 [The motion carried unanimously. The Respondent's 7 name is Quik-Stop Pharmacy of Barley Station, Inc.] * * * 8 9 MR. ESTERBROOK: 10 I move to accept the Consent Agreement at Case No. 23-54-004066. 11 MS. GETZEY HART: 12 13 Second. 14 CHAIRPERSON TALBOTT: 15 Any discussion? Call the vote. 16 17 Esterbrook, aye; Hart, aye; Claggett, 18 aye; Talbott, aye; Roussel, aye; Ritchie, 19 aye; Slagle, aye. 20 [The motion carried unanimously. The Respondent's 21 name is Ahmed Bachir, R.Ph.] 22 23 MR. ESTERBROOK: 24 I move to accept the Consent Agreement at 25 Case No. 22-54-012329.

14 MS. GETZEY HART: 1 2 Second. 3 CHAIRPERSON TALBOTT: 4 Any discussion? Call the vote. 5 Esterbrook, aye; Hart, aye; Claggett, 6 7 aye; Talbott, recuse; Roussel, aye; 8 Ritchie, aye; Slagle, aye. 9 [The motion carried. Theresa Talbott recused herself 10 from deliberations and voting on the motion. The 11 Respondent's name is Lech's Pharmacy.] * * * 12 13 MR. ESTERBROOK: 14 I move to accept the Consent Agreement at 15 Case No. 22-54-018675. MS. GETZEY HART: 16 17 Second. 18 CHAIRPERSON TALBOTT: 19 Any discussion? Call the vote. 20 21 Esterbrook, aye; Hart, aye; Claggett, 22 aye; Talbott, aye; Roussel, aye; Ritchie, 23 aye; Slagle, aye. 24 [The motion carried unanimously. The Respondent's 25 name is Praxis Specialty Pharmacy LLC dba Praxis Rx

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   Pharmacy.]
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   MR. ESTERBROOK:
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                 I move to accept the Consent Agreement at
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                 Case No. 20-54-008051.
   MS. GETZEY HART:
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7
                 Second.
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   CHAIRPERSON TALBOTT:
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                 Any discussion? Call the vote.
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                 Esterbrook, aye; Hart, aye; Claggett,
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                 aye; Talbott, aye; Roussel, aye; Ritchie,
13
                 aye; Slagle, aye.
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   [The motion carried unanimously. The Respondent's
15
   name is Timothy Rohrer.]
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   MR. ESTERBROOK:
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                 I move to accept the VRP Consent
19
                 Agreement at Case No. 23-54-012206.
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   MS. GETZEY HART:
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                 Second.
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   CHAIRPERSON TALBOTT:
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                 Any discussion? Call the vote.
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                 Esterbrook, aye; Hart, aye; Claggett,
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16 1 aye; Talbott, aye; Roussel, aye; Ritchie, 2 aye; Slagle, aye. 3 [The motion carried unanimously.] 4 5 MR. ESTERBROOK: I move to accept the Consent Agreement at 6 7 Case No. 22-54-002561. 8 MS. GETZEY HART: 9 Second. 10 CHAIRPERSON TALBOTT: 11 Any discussion? Call the vote. 12 13 Esterbrook, aye; Hart, aye; Claggett, 14 aye; Talbott, aye; Roussel, aye; Ritchie, 15 aye; Slagle, aye. 16 [The motion carried unanimously. The Respondent's 17 name is Erica L. Roberman, R.Ph.] * * * 18 19 Report of Board Counsel - Hearing 20 [A Formal Hearing was held from 11:02 a.m. until 21 11:43 a.m. in the Matter of the Petition for 22 Reinstatement of Thomas James Fortunato, R.Ph., Case 23 No. 23-54-011152.] 24 25 Report of Board Counsel - Regulatory Report

1 [Theresa M. Talbott, R.Ph., Chairperson, noted the
2 Board received comments concerning the general
3 revisions and would be discussed at the end of the
4 meeting.]

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Report of Board Counsel - Legislative Report

[Ariel E. O'Malley, Esquire, Board Counsel, noted

Senate Bill 910 was introduced on September 14 and

was referred to the Consumer Protection and

Professional Licensure Committee. She explained that

it would expand the Board's ability to expunge

certain offenses, such as disciplinary actions under

the Board's schedule of civil penalty offenses.

Ms. O'Malley mentioned the Board is currently limited to minor practice on lapsed license cases and continuing education violations but would be able to expunge offenses that come up on their civil penalty schedule if the legislation passes.

Ms. O'Malley noted House Bill 1661 was introduced on September 7 and amended on October 3, which addresses the inappropriate use of xylazine. She mentioned the bill also added language that largely amends the Drug Act and requires veterinarians to comply with Section 4 of the Pharmacy Act for the storage and protection of xylazine.

Ms. Getzey Hart requested more information concerning a bill that would take away the state's ability to schedule a drug differently and align them up with a federal list.

Ms. O'Malley offered to provide Senate Bill 959 on the report for the next meeting, further explaining that Pennsylvania would not have to reschedule items on the controlled substance list and would automatically follow the federal list.]

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Report of Board Counsel - Matters for Deliberation
MS. O'MALLEY:

In accordance with Executive Session deliberations, I believe the Board would entertain a motion to delegate the matter at item 20, Atlas Pharmacy & Miteshkumar Laljibhai Patel, R.Ph., Case Nos. 23-54-001963 & 23-54-001964, for a hearing to be conducted by a hearing examiner and to prepare a Proposed Adjudication.

21 MR. ESTERBROOK:

So moved.

23 MS. GETZEY HART:

24 Second.

25 CHAIRPERSON TALBOTT:

Any discussion on that motion? Call the vote.

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Esterbrook, aye; Hart, aye; Claggett,
aye; Talbott, aye; Roussel, aye; Ritchie,
aye; Slagle, aye.

7 [The motion carried unanimously.]

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9 MS. O'MALLEY:

Item 19 for Andrew Kuzy is being tabled for the next meeting because there was an error with the transcript, and by the time it was corrected, the Board did not have time to review the matter to appropriately deliberate.

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17 MS. O'MALLEY:

Item 21, <u>Precision Pharmacy and</u>

<u>Compounding Center</u>, is going to be scheduled for a Board hearing.

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22 Report of Board Counsel - Draft Adjudications and Orders

24 MR. ESTERBROOK:

I move to approve the Draft Adjudication

20 1 and Order for Mark Reinhard, Case No. 21-54-019496. 2 3 MS. GETZEY HART: 4 Second. 5 CHAIRPERSON TALBOTT: 6 Any discussion? Call the vote. 7 Esterbrook, aye; Hart, aye; Claggett, 9 aye; Talbott, aye; Roussel, aye; Ritchie, 10 aye; Slagle, aye. 11 [The motion carried unanimously.] 12 13 MR. ESTERBROOK: 14 I move to approve the Draft Adjudication 15 and Order for Pharmacy Services America, 16 Inc., t/d/b/a Pharmacy Services America, Case No. 21-54-016509. 17 18 MS. GETZEY HART: Second. 19 20 CHAIRPERSON TALBOTT: 21 Any discussion? Call the vote. 22 23 Esterbrook, aye; Hart, aye; Claggett, aye; Talbott, aye; Roussel, aye; Ritchie, 24 25 aye; Slagle, aye.

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   [The motion carried unanimously.]
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   MR. ESTERBROOK:
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                I move to accept the Draft Adjudication
 5
                and Order for Peter Grujich, Case No. 22-
                 54-010022.
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   MS. GETZEY HART:
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                Second.
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   CHAIRPERSON TALBOTT:
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                Any discussion? Call the vote.
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                Esterbrook, aye; Hart, aye; Claggett,
13
                aye; Talbott, aye; Roussel, aye; Ritchie,
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                aye; Slagle, aye.
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   [The motion carried unanimously.]
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   Report of Board Chairperson
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   [Theresa M. Talbott, R.Ph., Chairperson, informed
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   Board members that Dr. Roussel has agreed to serve as
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   their probable cause screening person until December
21
   when those committees are determined for next year.
22
        Chair Talbott addressed her attendance, along
23
   with Dr. Roussel, Ms. Getzey Hart, and Ms. Zimmerman,
24
   at the National Association of Boards of Pharmacy
25
   (NABP) District I and II Meeting at Atlantic City in
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September.

Dr. Roussel stated the interesting part of the meeting is it also has the deans of the colleges of pharmacy. She noted several different regulatory issues were presented, but one of the big things facing their profession is the lack of applicants to their pharmacy schools and the lack of people entering their profession.

Ms. Zimmerman mentioned that one of the most valuable things was interacting with other board members and administrative officers.

Ms. Getzey Hart stated District 2 did a very good job with getting the schools of pharmacy to have representation there. She mentioned that District 2 had faculty or someone else attend if a dean could not and was probably one of the best meetings with the pharmacy schools present. It is important for the schools to understand what their students will face upon graduation.

Chair Talbott stated District 2 decided to conduct a survey about the meeting to address the non-attendance. She noted David Bowyer from West Virginia ran the task force and pursued individuals to provide a response to the survey, which was great.

25 | She mentioned that District 2 also allowed for

interactive discussion.

Dr. Roussel informed everyone that the meeting in 2025 would be held in Delaware. She noted that PA pharmacy schools are stepping up to partner and to help them host their program because Delaware does not have any pharmacy schools. She also noted there was a session regarding health equity to ensure more health equity across all populations.

Chair Talbott addressed a discussion concerning stress in the workplace. She noted there was a summit held by the American Pharmacists Association (APhA), the American Society for Health-System Pharmacists (ASHP), and NABP in June. She stated the report could be found on any of those websites and is called Implementing Solutions Summit: Building a Sustainable, Healthy Pharmacy Workforce and Workplace.

Chair Talbott mentioned that she was hoping to discuss some of the regulatory hurdles the Board faces with the director of policy. She again mentioned the issue about stress in all aspects of healthcare, and the Board has taken a hard look at their day jobs and how pharmacists and staff could be assisted. She noted that one of the biggest issues is public service announcements to patients, noting

2.4

1 the incidence of violence against healthcare workers
2 in general has increased 4000% since COVID.]

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4 Report of Acting Commissioner

5 [Arion R. Claggett, Acting Commissioner, Bureau of 6 Professional and Occupational Affairs, informed Board 7 members that the Policy Director would be available

next month.

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Acting Commissioner Claggett reported receiving an invitation from Larry Jones, Executive Director, Pennsylvania Society of Health-System Pharmacists, to observe automation at a hospital and pharmacy site. He informed Mr. Jones that they accept his invitation and would like to attend sometime in the afternoon on December 18 instead of December 19.

Acting Commissioner noted the request for proposal (RFP) for the Pennsylvania Licensing System (PALS) replacement was released on September 28, 2023 and he will keep the Board updated as the process moves forward.]

21 ***

22 Report of Board Administrator

23 [Melanie Zimmerman, R.Ph., Board Administrator,

24 informed Board members that she is working on placing

25 some of the pharmacy business applications online. On

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2.5
   November 17, the PA Pharmacy Remodeling Application,
1
2
   PA Pharmacy Change in Location Application, and
3
   Pennsylvania Pharmacy Change in Manager Application
4
   would be online PALS applications available at
5
   www.pals.pa.gov and then the Board would no longer
6
   accept these as paper applications.]
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                              * * *
8
   Discussion Items
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   CHAIRPERSON TALBOTT:
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                 We met in Executive Session and discussed
11
                 items 27 through 34 with item 31 being
12
                 removed.
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                     Do we have any motions on those
14
                 items?
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   MR. ESTERBROOK:
16
                 I have a motion to approve discussion
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                 item 27, Dalal Kablan, to Review Intern
18
                 Hours.
   MS. GETZEY HART:
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20
                 Second.
21
   CHAIRPERSON TALBOTT:
22
                 Any discussion? Call the vote.
23
24
                 Esterbrook, aye; Hart, aye; Claggett,
25
                 aye; Talbott, aye; Roussel, aye; Ritchie,
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26
1
                 aye; Slagle, aye.
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   [The motion carried unanimously.]
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   MR. ESTERBROOK:
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5
                 I have a motion to approve discussion
                 item 28, Jennifer Kline, Review of
6
7
                 Pharmacist License Application.
8
   MS. GETZEY HART:
9
                 Second.
10
   CHAIRPERSON TALBOTT:
11
                 Any discussion? Call the vote.
12
13
                 Esterbrook, aye; Hart, aye; Claggett,
14
                 aye; Talbott, aye; Roussel, aye; Ritchie,
15
                 aye; Slagle, aye.
16
    [The motion carried unanimously.]
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18
   MR. ESTERBROOK:
                 I have a motion to deny item 29, Susan
19
20
                 Merenstein, Request to Extend USP 800
21
                 Enforcement Date.
22
   MS. GETZEY HART:
23
                 Second.
24
   CHAIRPERSON TALBOTT:
25
                 Any discussion? Call the vote.
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27 1 2 Esterbrook, aye; Hart, aye; Claggett, 3 aye; Talbott, aye; Roussel, aye; Ritchie, 4 aye; Slagle, aye. 5 [The motion carried unanimously.] * * * 6 7 MR. ESTERBROOK: 8 I have a motion to approve item 30, 9 Santhosh Mathew, Review of Pharmacist 10 License Application. 11 MS. GETZEY HART: Second. 12 13 CHAIRPERSON TALBOTT: 14 Any further discussion? Call the vote. 15 16 Esterbrook, aye; Hart, aye; Claggett, 17 aye; Talbott, aye; Roussel, oppose; 18 Ritchie, oppose; Slagle, aye. 19 [The motion carried. Christine Roussel and Tyler 20 Ritchie opposed the motion.] * * * 21 22 MR. ESTERBROOK: 23 I have a motion to approve discussion 24 item 32, Sahr Samuel Gbakima, Review of 25 Pharmacist License Application.

28 MS. GETZEY HART: 1 2 Second. 3 CHAIRPERSON TALBOTT: 4 Any discussion? Call the vote. 5 6 Esterbrook, aye; Hart, aye; Claggett, 7 aye; Talbott, aye; Roussel, oppose; 8 Ritchie, aye; Slagle, aye. 9 [The motion carried. Christine Roussel opposed the 10 motion.1 11 * * * MR. ESTERBROOK: 12 13 I have a motion to approve discussion 14 item 34, Walgreens Central Fill #21421, 15 Proposed Pennsylvania Pharmacy 16 Application. 17 MS. GETZEY HART: 18 Second. CHAIRPERSON TALBOTT: 19 20 Any discussion? Call the vote. 21 22 Esterbrook, aye; Hart, aye; Claggett, 23 aye; Talbott, aye; Roussel, aye; Ritchie, 24 aye; Slagle, aye. 25 [The motion carried unanimously.]

2 FYI Items

Theresa M. Talbott, R.Ph., Chairperson, referred to the Well-Being Index for Pharmacy Personnel August through October 2023, noting they are in the middle as far as stress. She reported no statistical difference from a practice standpoint between someone who works in a hospital or an independent pharmacy.

Chair Talbott informed everyone that NABP took a look at the updated competency standards and remapped the Multistate Pharmacy Jurisprudence Examination (MPJE) to those standards and found the test is still psychometrically sound. She reported fees are increasing for the North American Pharmacist Licensure Examination (NAPLEX) and the MPJE, effective 3/1/2024.

Chair Talbott noted the FDA is delaying enforcement of the Drug Supply Chain Security Act (DSCSA).

Ms. Getzey Hart asked who would be responsible for enforcement in the state of Pennsylvania.

Ms. O'Malley mentioned that there are many different entities involved from the licensing and department side, and it has not been settled yet. She noted the Board has a year to get their logistics

straight and the government also has a year.

Ms. O'Malley noted her attendance at an annual legal conference in Texas. She mentioned it gave some empathy for some of the frustrations licensees feel in dealing with issues in Pennsylvania and all of the different departments and bureaus licensees need to go to address their issues. She noted the DSCSA came up multiple times.

Ms. Getzey Hart noted it would impact pharmacies, too, because of being the pharmacy for the patient, but there is not that avenue of the wholesaler to the pharmacy because it does not rest under the Board. She again mentioned the year with no enforcement, noting there are some issues where they could not wait a year and need to keep moving forward. She suggested inviting Josh Bolin from NABP to provide a brief overview.

Ms. Getzey Hart commented that many independent owners have no idea about this, and much preparation is needed, including recordkeeping. She noted the importance of informing everyone of what is coming down the line.

Chair Talbott asked Mr. Reed to take it back to the Pennsylvania Pharmacists Association for discussion at the February meeting. She also asked

Mr. Jones to provide some information.

Chair Talbott suggested continuing the conversation for now and then inviting Mr. Bolin.

Ms. O'Malley noted that much education is needed on topics in general and not just the DSCSA. She also noted it was mentioned at the conference that everyone needs to do a better job of communicating with licensees and making them more aware of changes and advancements in the pharmacy field.

Chair Talbott commented that Mr. Bolin may already have something on the website that could be provided to Ms. Zimmerman.

Ms. O'Malley recommended working on a newsletter for the beginning of the year to inform licensees of things that are happening and what they need to be aware of for 2024.

Acting Commissioner Claggett commented that the newsletter could be placed on the Board's website, along with an email blast.]

[Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs, exited the meeting at 12:13 p.m.]

24 **

25 Report of Board Counsel (cont.) - Regulatory Report

[Theresa M. Talbott, R.Ph., Chairperson, referred back to item 17 on the agenda for a regulatory discussion.

Ms. O'Malley informed Board Members of recent restructuring of Board Counsel, noting they now have regulatory counsel, and Mr. Farrell would be working with Board Counsel to review pharmacy regulations.

Chair Talbott noted a comment from the Department of Education asking for the Board to confirm the proposed language for § 27.26 pharmacy internship and §27.52, graduates of foreign schools and noncitizens pertains to pharmacists, not pharmacy technicians, noting education requirements for pharm techs is found under § 27.702 pharmacy technician. She noted that to be correct.

Chair Talbott noted PSHP's issues under § 27.11, where pharmacy submitted an application and should be the owner or the applicant. She referred to "when there is a change in the name of a pharmacy, the pharmacy" and suggested replacing that with "pharmacy permit holder."

Chair Talbott referred to (d), shall submit an application for a name change on a form approved by the Board. She noted the Board left it that way because it does not apply to just a printed form

1 because it could be an electronic form.

Individuals in attendance noted difficulty finding the form and suggested putting the process in the newsletter.

Chair Talbott moved on to the next comment received from PSHP: She noted they want the 30 calendar days of the change of the name, while submission requirement is within 30 days, is a response required by the Board to approve or deny the name change.

Ms. Zimmerman stated the regulation does not require that and processing would fall under normal policy.

Ms. Getzey Hart commented that many people who apply have never looked at a blueprint and do not know what a floor plan looks like and it is a little different than processing another type of application.

Dr. Roussel stated a business seeking licensure for patient care deserves a timely evaluation as well because of the magnitude of what that application may stand for.

Ms. Getzey Hart commented that there are other circumstances where they do not get the full picture of what is being licensed, where there is something

else like on a floor plan that may delay that. She noted the Board approves the pharmacy building and the hospital pharmacy.

Mr. Jones stated they were looking for some kind of parameters for some formal response. He noted if there is an issue with the application that the Board is always responsive.

Ms. O'Malley addressed the next PSHP comment regarding how the regulations are written and more relevant for community pharmacies, noting any acquisition contract is going to decide the ownership and is not really a concern. She stated the regulation is not drafted to only address community pharmacies and does not exclude ownership of a hospital pharmacy, noting any kind of acquisition contract is going to decide who the owner of that pharmacy is and should not really be an issue.

Mr. Jones stated it is very much an issue, because if he builds a new pharmacy within his hospital, who is considered the owner, and also asked if the board changes or the CEO changes, is that considered the owner.

Mr. Michalowski commented that the reason for those questions in the limitations on prescribers who have ownership interests and have to ask if they have

- more than 10% interest. He noted in some entities
 there would not be because it would just be a board.

 He noted many hospitals are formed as charitable
 organizations and that typically applies more to
- retail pharmacies, where they have to ask to make sure people are not applying who are going to be self-directing care to themselves.
 - Mr. Jones asked whether the question could be asked differently, whether it is an inpatient facility versus an outpatient or retail pharmacy.

- Ms. O'Malley explained that it is not the issue of whether it is inpatient or outpatient and is the issue of the controller and whether it is other medical practitioners, like physicians, and the standard is outlined in the Pharmacy Act.
- Mr. Jones asked whether listing the board members to a hospital and putting zero ownership interest would suffice as meeting the ownership of the application.
- Ms. Zimmerman stated almost 99.9% of the time individuals are not the direct owner of any pharmacy because they create entities to protect individuals from financial burdens if something would happen. She stated they do ask what the type of owner is depending on the pharmacy and then expect that they

list the owner, where somebody says it is hospital owned, they expect to see the owner listed as a hospital. She explained that depending on the choice of ownership, they would want to know the members of an LLC and who the officers are for a corporation.

She again noted that individuals are not normally listed as the direct owner.

Ms. Zimmerman noted there is a question asking if anybody holds more than 10% interest or stock in the direct owner and that goes back to where they are looking to make sure there are no physicians or medical practitioners. She noted an applicant answering "no" to that question, when they look at the officer information, they expect to see no one listed there with more than 10% and zero is an acceptable number as long as it matches the response to the question regarding whether anybody holds more than 10% interest.

Chair Talbott referred to an issue under § 27.11 and is another Board-approved form, noting it is on the website and Ms. Zimmerman would tell them how to find it.

Chair Talbott addressed another PSHP comment under section 27.26, regarding internship hours. She noted prior discussion with Dr. Roussel, where it is

an issue if they could not validate the intern hours accrued at an out of state Accreditation Council for Pharmacy Education (ACPE) accredited College. She noted they accept 1500 hours from an ACPE-accredited Pharm.D. program.

Ms. Zimmerman explained that there should not be an issue with intern hours for anyone graduating with a Pharm.D. degree from an ACPE-accredited school of pharmacy because when their education comes in, the Board is accepting all 1500 hours, which is part of the education verification form. She explained that the only individuals who may have issues and may have to submit hours earned outside of school are graduates of foreign pharmacy schools.

Chair Talbott referred to PPA's first comment under § 27.11 about change in ownership, where a joint form is filed with the board when a change in ownership occurs and none of the current owners retain any ownership interest. The PPA feels it is unnecessary to require the former owner and the new owner to submit both because that could require two submissions. The PPA suggested entertaining when a complete change in ownership occurs and none of the current owners retain any ownership interest, either the former and/or new owner.

Ms. Zimmerman stated they are currently only tracking the direct owners and the individuals or entities who hold stock or interest in the direct owner. She mentioned that any additional tiers in a corporate tier structure, they consider them too far removed and do not ask for any information, so the only information they transfer to other government agencies is the direct owner changes or controlling interest changes.

Mr. Jones explained that change in ownership and change in PIC in § 27.11 gets interpreted the same way. He stated a change in ownership to joint application makes perfect sense, but a change in PIC is not going to be a joint application because one is ceasing their liability as of such and such a date due to separation of employment or in charge of that store while the other is coming on board. He believed people interpret stuff in the statute and needs clarified.

Ms. Zimmerman stated the only person signing off on that application is the current owner when there is a change in controlling interest, because the current owner remains the same. She noted it is a change in ownership when there is a former owner and a new owner and that is when it is a dual

application.

Ms. O'Malley explained that it is a joint application and should stay that way.

Chair Talbott referred to (g), if the pharmacist in charge ceases to hold that position, the pharmacy permit holder shall inform the Board in writing on a Board-approved form of this fact and of the new pharmacist in charge not more than 30 days later. If the Board does not object within 30 days of notification, the new pharmacist in charge may be deemed approved.

Chair Talbott referred to PPA's comments, where 30 days is limiting and potentially discriminatory in the case of a short-term disability. She stated they doubled the 15 days because they heard from licensees that it was not enough time and want to make sure to protect patient safety.

Chair Talbott referred to § 27.12 practice the pharmacy delegation of duty. She noted the concern is the potential interpretation (by an inspector or PIC) that this is intended to require separate protocols for each individual technician employer, rather than one protocol covering with all duties listed that a technician may perform.

Chair Talbott stated there are no changes to that

language. She commented that if she has six techs that work for her, she needs to have a protocol for each one, and if there is something that one can do that the other cannot, then there should be enumeration on that.

Chair Talbott referred to § 27.18 Standards of Practice. She noted they did their best as far as when the pharmacist needed to stop filling that prescription and how they could make sure that the patient had access to medication if they needed it. She noted they tried to make sure they were taking care of the patient for up to 90 days from the date the prescriber died.

Chair Talbott explained that they also added that no prescription can be knowingly filled or refilled for a patient which prescription was written for use by a prescriber who no longer holds an active license to practice and provided a definition of active, active retired, or active on probation license.

Chair Talbott noted PPA had comments on § 27.18(j). She stated the Board was concerned with the ability to partially fill a controlled substance, so they copied 21 CFR §1306.13, which addresses multiple partial fills as long as they do not go over the full quantity. She noted their comment is it

cannot be refilled for more times for more than the full prescribed quantity in a six-month period from the date of the prescription and to include that because it would help to eliminate concerns. She noted they already included that because they cited CFR \$1306.13 and CFR \$1306.23.

Chair Talbott referred to § 27.19 Prospective

Drug Review and Patient Counseling (d) offer to

counsel, a pharmacy shall provide toll-free telephone

service or other means of communicating with the

pharmacist if its primary patient population is

beyond the local or toll-free exchange.

Chair Talbott noted the comment suggested elimination of the "toll-free number" since these are mostly out of of use. She noted that would be left in, and they also have other means.

Chair Talbott referred to the comment for § 27.18

Pharmacy Interns, noting while they do not anticipate a change in general revisions given the efforts of schools of pharmacy for this regulation, PPA expresses concern. She noted discussion at the NABP District Meeting about the lack of practical experience graduates have because all their hours are being counted from the curriculum.

Chair Talbott noted another comment under

§ 27.102, statement of policy on return to stock of undelivered medication. She stated the current policy is 6 months, and they are changing the 6 months to 12 months from the date the drugs were first prepared for dispensing.

Chair Talbott noted their concern is lack of consistency among inspectors regarding drug expiration dates within 30 days of the date of inspection visit, where there must be consideration of staffing issues, labor demands during peak hours, staff sick time, and internal pharmacy policies for regular review.

Chair Talbott stated is true and many of the cases she recused from revolved around expired drugs on the shelf. She thinks they should not be dispensing a drug if it expires within 30 days of an inspection visit.

Ms. O'Malley referred to § 27.26(i) regarding pharmacy preceptors. She noted an issue that came up recently where they realized the regs are not exactly clear about the termination of that relationship. She suggested changes to clearly delegate the responsibility either to the preceptor or the intern to submit something.

Ms. Zimmerman explained the current process. She

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stated when a preceptor completes an intern
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   experience reporting form and then the intern submits
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   it, there are questions on the form to ask whether
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   they need to separate the relationship or continue
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   with the relationship and then the Board office staff
   ends the association, if appropriate. She noted they
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7
   also have the pharmacy intern application, where they
   ask the preceptor if they are serving as preceptor
   for another student, and if they say "no" and they
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   have an association on record, the Board office staff
   removes that association and notifies the other
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   intern that they do not have a preceptor anymore.
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   She noted if a preceptor or intern writes to them
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   through PALS, they would end the relationship that
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   way too.
             She mentioned that in the past it was more
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   the intern experience reporting form that
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   accomplished this, but now that they are accepting
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   all school hours, they are not receiving as many
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   forms. 1
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                              * * *
21
   Adjournment
22
   MR. ESTERBROOK:
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                Motion to adjourn.
24
   MS. GETZEY HART:
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                Second.
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1 2 3		STATE BOARD OF PHARMACY REFERENCE INDEX	
4 5 6		November 7, 2023	
6 7 8	TIME	AGENDA	
9	9:00	Executive Session	
11 12	10:30	Return to Open Session	
13	10:34	Official Call to Order	
14 15	10:34	Pledge of Allegiance	
16 17	10:34	Emergency Announcement	
18 19 20 21	10:35	Introduction of Board Members/Board Staff/Audience	
22 23	10:40	Approval to the Agenda	
24 25	10:40	Approval of Minutes	
26 27	10:41	Report of Board Prosecution	
28 29 30	11:02 11:43	Formal Hearing - Thomas James Fortunato, R.Ph.	
31 32	11:44	Report of Board Counsel	
33 34	11:51	Report of Board Chairperson	
35	11:57	Report of Acting Commissioner	
36 37	11:58	Report of Board Administrator	
38 39	11:59	Discussion Items	
40	12:03	FYI Items	
42 43	12:13	Board Counsel (cont.)	
44 45 46 47 48	12:52	Adjournment	