State Board of Pharmacy August 27, 2024

Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson

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BOARD MEMBERS:

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Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs 10 Eric Esterbrook, R.Ph., Vice Chairperson 11 Janet Getzey Hart, R.Ph., Secretary

12 John R. Slagle, R.Ph. 13 14 15

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49 50 Tyler W. Ritchie, Esquire, Deputy Attorney General, Office of Attorney General

Theresa M. Talbott, R.Ph.

BUREAU PERSONNEL:

Shana M. Walter, Esquire, Senior Board Counsel Sean C. Barrett, Esquire, Board Counsel Ray J. Michalowski, Esquire, Senior Board Prosecutor

Nathan C. Giunta, Esquire, Board Prosecution Liaison Caroline A. Bailey, Esquire, Board Prosecutor

Christina Townley, Director of Operations, Bureau of Professional and Occupational Affairs Sara Trimmer, Pharm.D., R.Ph., Executive Secretary

Nichole Wray, Division Chief, Health Licensing Division

Marc Farrell, Esquire, Regulatory Counsel, Office of Chief Counsel, Department of State Steven Zahn, Pharmacy Inspector, Bureau of Enforcement and Investigation, Department of State

ALSO PRESENT:

Kerry Maloney, Esquire, Associate Counsel, University of Pittsburgh Medical Center

Larry Jones, Pennsylvania Society of Health-System Pharmacists Member

Jill Rebuck, Executive Director, Pennsylvania Society of Health-System Pharmacists

Anthony Bixler, WellSpan York Hospital/Pennsylvania Society of Health-System Pharmacists

Jennifer Sullivan, Clinical Pharmacist, WellSpan York Hospital

Samuel Ludlow PharmD/MBA, Walgreens

James Reed, Pharmacy Regional Manager, Weis Markets

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ALSO PRESENT: (cont.)

Chenell Donadee, MD, MBA, Associate Medical Director of the Pharmacy Service Line, University of Pittsburgh Medical Center

Rebecca Taylor, Pharm.D., Vice President, Pharmacy Services, University of Pittsburgh Medical Center Brett Rodgers, Senior Manager for Pharmacy

Automation, University of Pittsburgh Medical Center Erik Hernandez, PharmD, MHA, BCPS, Vice President of Pharmacy, University of Pittsburgh Medical Center Central Region

Sarah Klinger, Legal Extern, University of Pittsburgh Medical Center

Katherine Medei, Area Healthcare Supervisor NJ/PA, Walgreens

Emily Kryger, PharmD, American Society of Consultant Pharmacists

Natalie Klek, Executive Fellow, Pennsylvania Pharmacists Association

Tracey Sawyer, Label Content Manager, Regulatory Affairs, Mission Pharmacal

Geoffrey Christ, Senior Pharmacy Compliance Manager, Chewy Pharmacy

29 Michelle Attai

Tiffany Booher, MA, LPC, CAADC, CIP, CCSM, Director, Peer Assistance Monitoring Programs; Program Director, Physicians' Health Program, Pennsylvania Medical Society

Bryan Dunwoody, Manager Pharmacy Compliance, Giant Pharmacy

Christina Antone

Susan DelMonico, R.Ph., JD

Sarah Everingham, MJ, CCEP, CPhT, Cardinal Health

Joshua Finger, PharmD, Enclara Pharmacia

Grace Fisher, Regional Pharmacy Manager, Giant Food Stores, LLC

Jacquelyn Sassaman, Pentec Health

Jessica Adams, PharmD, BCPS, AAHIVE, Scientific Director, Infectious Diseases at Clinical Care Options

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

Daniel Longyhore, System Director, Knowledge Management for Pharmacy at Geisinger

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(cont.) ALSO PRESENT:

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34 35 Blake Mancuso, PharmD, Penn Medicine Ultan McGlone, Pharmacist Clinician/Clinical Pharmacy Specialist

Haide Sorial, Advanced Pharmacy Practice Experience Student, Pennsylvania Pharmacists Association Megan Ammon, PharmD, BCMTMS, Clinical Program Coordinator at Weis Markets

Veronica Ng, RPh, CVS Health

Christopher Miller, Pharm.D., Giant Eagle Nicole Fidler, Associate, Malady & Wooten

Olivia Sugarman, Ph.D., Johns Hopkins Bloomberg School of Public Health

Piri Pantoja Jr., Deputy Director of Legislative Affairs, Department of State

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

Laura Romeo, Pharmacist-in-Charge at ConnectiveRx, Careform Pharmacv

Scott Young

Grace Sesi, Executive Director, Regulatory Affairs at CVS Health/Chairperson, Michigan Board of Pharmacy Cory Ulisse, PharmD, Pharmacy Clinician Services Victoria Elliott, RPh, MBA, CAE, Chief Executive Officer, Pennsylvania Pharmacists Association

Zoe Soslow, Technical Advisor, Pennsylvania Overdose Prevention Program, Vital Strategies

Dana Kurzer-Yashin, Program Manager, Pennsylvania Overdose Prevention Program, Vital Strategies Lauren Gusherowski, Sargent's Court Reporting Service, Inc.

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State Board of Pharmacy

August 27, 2024

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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.]

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The regularly scheduled meeting of the State

14 | Board of Pharmacy was held on Tuesday, August 27,

15 2024. Eric Esterbrook, R.Ph., Vice Chairperson,

16 called the meeting to order at 10:30 a.m.

17 Vice Chair Esterbrook informed all that he would

18 be chairing the meeting as Chair Roussel is

19 participating virtually.

20 ***

21 [Sean C. Barrett, Esquire, Board Counsel, informed

22 everyone that the meeting was being recorded, and

23 those who continued to participate were giving their

24 | consent to be recorded.

25 Mr. Barrett also noted the Board entered into

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Executive Session for the purpose of conducting
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2
   quasi-judicial deliberations on a number of matters
3
   that are currently pending before the Board and to
4
   receive the advice of counsel.]
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5
   Introduction of Board Members/Attendees
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   [Vice Chair Esterbrook requested an introduction of
   Board members and attendees. A quorum of Board
   members was present.]
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11
   Approval of Minutes
   VICE CHAIR ESTERBROOK:
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13
                 The first item on our agenda is to
14
                 approve the minutes from July 30.
15
                 additions, corrections, or anything?
16
   MS. TALBOTT:
                 I'll make a motion that we approve the
17
18
                minutes from July 30.
   MS. GETZEY HART:
19
20
                 Second.
21
   VICE CHAIR ESTERBROOK:
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                Roll call.
23
24
                Esterbrook, aye; Hart, aye; Slagle, aye;
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                 Talbott, aye; Claggett, aye; Ritchie,
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1 aye; Roussel, aye.

2 [The motion carried unanimously.]

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4 Report of Board Prosecution

5 | [Nathan C. Giunta, Esquire, Board Prosecution

6 Liaison, presented the Consent Agreements for Case

7 No. 21-54-019000; Case Nos. 22-54-002470, 21-54-

 $8 \mid 013947$, & 22-54-002468; Case No. 22-54-007985; and

9 Case No. 22-54-012665.

Mr. Giunta presented the Consent Agreement for

11 | Case No. 24-54-010815.

12 Mr. Barrett noted Vice Chair Esterbrook recused

13 himself, did not participate in any deliberations,

14 and would not vote on this matter.]

15 MR. BARRETT:

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Based on the presentation of prosecution,

do any Board members wish to return to

18 Executive Session for further

19 deliberation? Hearing none.

20 Based on Executive Session

deliberations, I believe the Board Vice

22 Chair would entertain a motion to approve

the Consent Agreements at agenda item 4,

Case No. 21-54-019000; agenda item 5,

25 Case Nos. 22-54-002470, 21-54-013947, &

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                 22-54-002468; agenda item 6, Case No. 22-
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2
                 54-007985; and agenda item 7, Case No.
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                 22-54-012665.
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   MS. TALBOTT:
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                 I'll make that motion.
   MS. GETZEY HART:
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7
                 Second.
8
   VICE CHAIR ESTERBROOK:
9
                 Roll call vote.
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11
                 Esterbrook, aye; Hart, aye; Slagle, aye;
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                 Talbott, aye; Claggett, aye; Ritchie,
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                 aye; Roussel, aye.
14
   [The motion carried unanimously. The Respondent's
15
   name at agenda item 4 is Todd Andrew Goodman, R.Ph.;
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   item 5, Francis H. Ranier and Ranier's Rx Laboratory;
17
   item 6, Walgreens Pharmacy Services Midwest, LLC DBA
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   Walgreens #4580-2; and item 7, Kimberly Anna Huynh,
19
   R.Ph.]
                              * * *
20
21
   MR. BARRETT:
22
                 Agenda item 8. Board member Easterbrook
23
                 did recuse himself from any deliberation
                 in this matter and any discussions with
24
25
                 the Board.
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Based on Executive Session 1 2 deliberations, I believe the Board Chair 3 would entertain a motion to adopt the 4 Consent Agreement at Case No. 24-54-5 010815. 6 MS. TALBOTT: 7 I'll make that motion. 8 MS. GETZEY HART: 9 Second. 10 VICE CHAIR ESTERBROOK: 11 Call to a vote. 12 13 Esterbrook, recuse; Hart, aye; Slagle, 14 aye; Talbott, aye; Claggett, aye; 15 Ritchie, aye; Roussel, aye. 16 [The motion carried. Eric Esterbrook recused himself 17 from deliberations and voting on the motion. 18 Respondent's name at agenda item 8 is Jeffrey T. 19 Swanberry, R.Ph.] * * * 20 21 Report of Board Counsel - Matters for Deliberation 22 MR. BARRETT: 23 Agenda item 10. Board member Esterbrook 24 recused himself from any discussions or 25 participation in this matter with the

10 1 Board. Based on Executive Session 2 3 deliberations, I believe the Board Chair 4 would entertain a motion to remand item 5 10 to the hearing examiner for 6 proceedings in this matter. 7 MS. TALBOTT: 8 I'll make that motion. 9 MS. GETZEY HART: 10 Second. 11 VICE CHAIR ESTERBROOK: 12 Call to a vote. 13 14 Esterbrook, recuse; Hart, aye; Slagle, 15 aye; Talbott, aye; Claggett, aye; Ritchie, aye; Roussel, aye. 16 17 [The motion carried. Eric Esterbrook recused himself 18 from deliberations and voting on the motion.] * * * 19 20 Report of Board Counsel - Proposed Adjudications and Orders 21 22 MR. BARRETT: 23 Based on Executive Session deliberations 24 at item, I believe the Board Chair would 25 entertain a motion to adopt the Proposed

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                 Adjudication and Order at item 11, Case
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                 No. 23-54-006922, Allegheny Discount
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                 Pharmacy.
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   MS. TALBOTT:
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                 I'll make that motion.
   MS. GETZEY HART:
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7
                 Second.
8
   VICE CHAIR ESTERBROOK:
9
                 Call to a vote.
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11
                 Esterbrook, aye; Hart, aye; Slagle, aye;
12
                 Talbott, aye; Claggett, aye; Ritchie,
13
                 aye; Roussel, aye.
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   [The motion carried unanimously.]
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   MR. BARRETT:
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                 At item 12, Sarah Elizabeth Stroud, Case
18
                 No. 23-54-017501, Chair Roussel recused
                 herself from any deliberations or
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20
                 discussion in this matter.
                     Based on Executive Session
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22
                 deliberations, I believe the Chair would
23
                 entertain a motion to adopt the Proposed
24
                 Adjudication and Order in this matter.
25
   MS. TALBOTT:
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12
1
                I'll make that motion.
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   MS. GETZEY HART:
3
                Second.
   VICE CHAIR ESTERBROOK:
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 5
                Call to a vote.
 6
7
                Esterbrook, aye; Hart, aye; Slagle, aye;
8
                Talbott, aye; Claggett, aye; Ritchie,
9
                aye; Roussel, recuse.
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   [The motion carried. Christine Roussel recused
11
   herself from deliberations and voting on the motion.]
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   Report of Board Chairperson
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   [Christine Roussel, Pharm.D., BCOP, BCSCP,
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   Chairperson, noted being actively engaged in hosting
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   the National Association of Boards of Pharmacy
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   (NABP)/American College of Clinical Pharmacy (ACCP)
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   Districts 1 and 2 Meeting, which will be held in the
   fall of 2025. She stated their subcommittee
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   continues to work to identify a hotel, and they have
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   been partnering with the colleges of pharmacy on
22
   behalf of NABP.
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        Chair Roussel reminded everyone that the
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NABP/ACCP Districts 1 and 2 Meeting will be held in

Boston on October 6, 2024.

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Chair Roussel looked forward to talking to Mr.
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   Farrell about scheduling time for the regulatory work
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   sessions in October and December 2024.]
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   Report of Acting Commissioner
   [Arion R. Claggett, Acting Commissioner, Bureau of
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   Professional and Occupational Affairs, informed
   everyone that the next Board meeting will be held at
   Wilkes University on October 22, 2024, in a hybrid
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   format at Wilkes and online on Microsoft Teams.
   mentioned that the Board agenda and Board website
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12
   will be updated after the meeting with the exact
13
   location.1
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                              * * *
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   Report of Executive Secretary - No Report
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   [Sara Trimmer, Pharm.D., R.Ph., Executive Secretary,
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   had nothing to report.
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        Ms. Talbott asked how the renewals are coming
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   along since the process had been smooth and easy.
20
   She also mentioned that there had not been any
21
   glitches with new licenses.
22
        Dr. Trimmer reported 42% of pharmacists have
23
   completed the renewal process.]
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   Report of Board Members - No Report
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assistance and evaluation.

2 Appointment - Vital Strategies/Johns Hopkins
3 University Presentation
4 [Olivia Sugarman Ph.D. Johns Hopkins Bloomh

[Olivia Sugarman, Ph.D., Johns Hopkins Bloomberg

School of Public Health, informed Board members that

she works for the Bloomberg Overdose Prevention

Initiative, which is a Bloomberg Philanthropies
funded multistate initiative to prevent overdose

through implementation activities through technical

Dr. Sugarman stated the Initiative is in seven states, including Pennsylvania, and work in close partnership with Vital Strategies, which is the implementation and technical assistance hub of the enterprise to do various research and evaluation activities to examine gaps in the information space in each state.

Dr. Sugarman explained their proposal to conduct a survey of pharmacists licensed in Pennsylvania to ascertain experiences in stocking and dispensing buprenorphine to treat an opioid use disorder. She noted buprenorphine is one of the three Food and Drug Administration (FDA)-approved medications to treat an opioid use disorder and is incredibly effective at improving the health of people living with an opioid

use disorder.

Dr. Sugarman reported that the odds of a future nonfatal overdose decreases in some places by 5-10%, even with one additional month of staying on buprenorphine. She mentioned that one of the benefits of buprenorphine is that it is prescribed by a healthcare provider and can be filled in a pharmacy, as opposed to methadone, which requires high restrictions and going to a location each day.

Dr. Sugarman addressed barriers to accessing buprenorphine in pharmacies. She noted there has been a focus on lowering barriers for prescribers giving people buprenorphine for an opioid use disorder. She reported issues with pharmacies not having buprenorphine in stock or not being dispensed.

Dr. Sugarman stated approximately 58% of pharmacies reported stocking buprenorphine, noting Pennsylvania was at approximately 60%. She noted 64% of chain pharmacies reported having buprenorphine in stock as opposed to 35% of independent pharmacies. She mentioned that pharmacies that have buprenorphine on hand may not be able to adequately meet patient need.

Dr. Sugarman stated some of the research existing concerning the barriers for buprenorphine stocking

- 1 and dispensing focuses on organizational anti-
- 2 diversion policies, like not accepting out-of-state
- 3 prescriptions and pharmacists' attitudes and
- 4 knowledge of people who use drugs and buprenorphine.
- 5 | She noted the goal of the survey is to fill that gap
- 6 | concerning wholesaler or distributor caps or ordering
- 7 thresholds on buprenorphine stocking, dispensing, and
- 8 ordering.
- 9 Dr. Sugarman explained that the purpose of the
- 10 study would be to understand Pennsylvania
- 11 pharmacists' experiences with stocking and dispensing
- 12 buprenorphine for an opioid use disorder with the
- 13 | goal of examining the effects of real and perceived
- 14 caps on buprenorphine stocking, dispensing, and
- 15 ordering; identifying barriers; and to evaluate
- 16 pharmacists experience, knowledge, attitudes, and
- 17 | beliefs about buprenorphine in Pennsylvania
- 18 pharmacies.
- Dr. Sugarman stated they are searching for
- 20 pharmacists who are licensed to practice in
- 21 | Pennsylvania and who practice in outpatient settings
- 22 exclusively and will randomly select pharmacists to
- 23 participate as kind of an arbitrary stratification.
- 24 | She noted they are looking for about 500 pharmacists
- 25 from each of the five Pennsylvania Pharmacists

Association regions to complete the survey.

Dr. Sugarman noted it is a 15- to 20-minute online survey and anyone who participates will receive \$50. She hoped to launch in September 2024 and implement the survey in October 2024 for about a month. She noted only studying Pennsylvania pharmacies at the moment in the hopes of improving communication between multiple players who impact ordering, stocking, and dispensing of buprenorphine; inform pharmacist licensure requirements, and to inform policy and practice options to enhance buprenorphine access.

Dr. Sugarman stated they plan to present a preliminary and final report to the State Board of Pharmacy and any stakeholders who are interested, writing an executive summary report, and to summarize their results in an academic publication.

Dr. Sugarman asked Board members to review the packet of materials to be included in the survey for any omissions and relevance of the questions to make sure the language is copasetic with the standards of practice in the state. She also asked Board members to encourage participation in the survey with a brief notice on the Pennsylvania State Board of Pharmacy website or by word of mouth.

Dr. Sugarman provided a letter of support and contact information.

Ms. Talbott asked Dr. Sugarman how they would handle a particular area of the state not responding.

Dr. Sugarman explained that they hoped to avoid that with stratified random sampling and would also send reminder emails at least twice but then pivot if people are not responding from other areas.

Acting Commission Claggett commented that the next step would be to review the materials and follow up with Dr. Sugarman.

Dr. Sugarman clarified that the timeline can be flexible, and their goal is to have a final product by the end of the year. She noted their request is for Board members to say that they had heard about this and hopefully would be in support after discussing the materials.

Chair Roussel thanked Dr. Sugarman for doing thoughtful research on something that affects patient care in Pennsylvania.]

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22 Appointment - UPMC Technology-enabled Pharmacist

23 | Verification Presentation

24 [Sean C. Barrett, Esquire, Board Counsel, informed

25 UPMC that there may be discussion of foreign

regulation after reviewing the information provided.

He stated the Board cannot not give advisory opinions as to its regulation and do not preapprove conduct, so any mention of the regulations by the presenter is not expressly supported by the Board. He informed

UPMC to consult with their own attorneys if they have

a question on a regulation.

Kerry Maloney, Esquire, Associate Counsel,
University of Pittsburgh Medical Center, presented to
the Board to discuss provisions in the State Board of
Pharmacy Act and regulations concerning direct and
immediate personal supervision of pharmacy
technicians, including a review of the prescription
or drug order by the pharmacist and the final
verification of the final product by the pharmacist.

Mr. Maloney stated UPMC is not looking for an advisory opinion, but asking for support to open up the Pharmacy Act, or a new regulatory package. He mentioned that they may request a statement of policy as far as an explanation, description, or guidance for licensees in the future.

Rebecca Taylor, Pharm.D., Vice President,

Pharmacy Services, University of Pittsburgh Medical

Center, provided a summary of her professional

background. She stated UPMC's paramount concern is

patient safety in terms of ensuring the patient receives the right product at the right time. She noted that 90% of medications in a hospital can come from an automated dispensing cabinet.

Dr. Taylor stated the order verification or the clinical review will always happen by a pharmacist in their electronic medical record (EMR). She mentioned that pharmacists in Pennsylvania look at an order and validate the patient's profile and all of the things allowed under an institutional protocol.

Dr. Taylor explained that they are talking about the interpretation of when and where a pharmacist validates a drug that may come in a unit dose that is barcoded, where a pharmacist in a technology-enabled pharmacist verification workflow owns every portion and the National Drug Code (NDC) of that drug is attached to the drug and validates it.

Dr. Taylor noted situations where the barcode is ripped off or the barcode on a drug is not working, where a pharmacist would be involved in validating the drug. She expressed the importance of having processes and systems built to make sure they get the patient the correct medication.

Dr. Taylor believed they would be facing a pharmacist shortage and reported a 14% decrease in

applications for pharmacy students entering PharmD programs. She also believed in the ability of highly trained pharmacy technicians to help pharmacists deliver medications to patients.

Dr. Taylor stated Dr. Hernandez found through internal studies that 7 hours a day of a pharmacist's time is dedicated to practices that a barcode could check very safely 99% of the time. She requested Board members to consider things pharmacists can be doing instead that involves transitions of care, rounding, and helping the patient transition to home.

Dr. Taylor mentioned that a pharmacist may be on the phone for over an hour with a pharmaceutical company because of the complexity of specialty medications and limited distribution channels. She asked for the Board's collaboration and partnership and maybe a future regulatory discussion to continue the dialogue around how they could leverage technology.

Chenell Donadee, M.D., MBA, Associate Medical Director of the Pharmacy Service Line, University of Pittsburgh Medical Center, addressed the critical and vital role that the pharmacists play in patient care in a hospital setting. She mentioned that she has been working with an excellent clinical pharmacist

who has been able to round with them daily in the Intensive Care Unit.

Dr. Donadee commented that patients have become more complex, far sicker, and the medications and medication regimens have become far more complex.

She mentioned struggling to provide the same level of care when they do not have the clinical pharmacist with them on the team.

Dr. Donadee stated there are clinical pharmacists all over the hospital with a variety of deep knowledge in different spaces, and they are a critical part of that patient care team.

Dr. Donadee addressed the pharmacy service line and highlighted some of the areas where pharmacists have been absolutely critical. She mentioned that drug shortages have been a major problem over the past couple years and expressed a concern that physicians may not be able to deliver patient care.

Dr. Donadee referred to chemotherapy shortages, where there have been times over the last couple of years, where they were concerned whether patients would be able to get their chemotherapy. She noted the importance of having pharmacists help them mitigate the shortages, decide what they can swap out, and help find additional product, which is

absolutely critical to patient care.

Dr. Donadee addressed formulary management, noting the complexity of the medication, insurance coverage, and modes of delivery. She also noted the importance of maintaining their formulary and keeping up with the science so that patients are receiving the best medications and treatment at the lowest cost.

Brett Rodgers, Senior Manager for Pharmacy
Automation, University of Pittsburgh Medical Center,
stated UPMC is focusing on a fully automated or fully
technology-assisted institutional pharmacy to provide
different steps in various sections of the workflow.

Mr. Rodgers referred to the Drug Supply Chain Security Act (DSCSA) regulations and all of the scanning that is going to be mandated in the relatively near future. He noted it to be just one scan of many that happens on arrival into an institutional pharmacy that is also being scanned into their electronic health record (HER) to make sure it works for the nurse at the time of arrival into the facility.

Mr. Rodgers explained that it would also be scanned in the automation system, maintaining the inventory in the central pharmacy itself to be double

checked. He noted the same for the automated dispensing cabinets or the anesthesia workstations, where there will be another scan so that the drug is scanned four times on arrival into the pharmacy.

Mr. Rodgers provided an overview of the workflow diagram that highlights a dispensing cabinet workflow versus a central pharmacy dispensing workflow, noting one is where the destination is the nurse pulling from a cabinet and the other one is where the drug has a patient label on it.

Mr. Rodgers noted the orange is where a pharmacist is engaged in the task, where a licensed pharmacist is performing that function, and purple is a scan where it will invoke the upper part of that workflow.

Mr. Rodgers explained, if a technician scans something out of that software system and it fails, it invokes that workflow, where a pharmacist would have to validate the NDC and verify the order in the electronic health record (EHR) that flows by profile to the dispensing cabinet.

Mr. Rodgers noted the nurse has to select the patient and select the order to be able to dispense it from the cabinet, unless it is an emergency medication. He highlighted that the pharmacist had

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been directly or peripherally involved in the
validation of the medication before it made it to the
nursing unit.

Mr. Barrett commented that Kansas seems to be the only state that has a specific regulation on this topic and asked whether there are other jurisdictions identified or whether there is currently an absence.

Mr. Rodgers explained that he would have to look at that, because those are meant to be examples. He mentioned that Mr. Barrett would be looking up anything formal that would come through anyway, especially the surrounding states.

Vice Chair Esterbrook commented that the Board is reviewing part 2 and changing the regulations at some point, because they were developed between 2009 and 2012, where the technology and functions did not yet exist, which is why they started with the presentations back in February. He mentioned that neighboring states and other places have been updated because of the technology, and Pennsylvania is behind the eight ball.]

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Report of Board Counsel - Regulatory Report

[Marc Farrell, Esquire, Regulatory Counsel, Office of
Chief Counsel, Department of State, addressed the

draft final annex and final preamble for the pharmacy
tech regulations. He noted changes were made to the
annex as presented at the last meeting. He also
noted the preamble now includes a summary of
comments that were received, along with the Board's
responses.

Mr. Farrell referred to prior Board discussion at the last meeting about the possibility of adding in the Act 77 changes for immunizations, noting it could be added to the package. He mentioned that they are not supposed to expand the scope of regulations midstream; however, Act 77 would not take effect until November 14, 2024, and the regulations cannot be filed until after that.

Mr. Farrell informed Board members that Counsel would soon send it to the Governor's Office for review if the Board adopts the preamble and the annex. He noted they should be able to deliver it to the Independent Regulatory Review Commission (IRRC) and the committees by mid-October 2024, even if they do not receive approval from the Governor Shapiro's Office until early October or late September 2024.

Mr. Farrell mentioned that they have to get it to IRRC 30 days before their meeting on November 21, 2024, for approval and then the Office of Attorney

General for a 30-day review period. He noted the Legislative Reference Bureau (LRB) has ten days to publish the regulations as final, which would be around January 2025.

Ms. Talbott asked Mr. Farrell whether the House Professional Licensure Committee's (HPLC) and the Senate Professional Licensure Committee (SPLC) have to review the regulation.

Mr. Farrell stated they did not receive comments from the committees during the proposed phase but will have a chance to review it again for 20 days in the final stage. He mentioned that the committees are expected to adjourn around November 30 and believed they would have already commented during the proposed stage.

Mr. Farrell also provided a summary of the Independent Regulatory Review Commission, noting their function is to review regulations to ensure it is in the best interest of the public.]

20 MS. TALBOTT:

I will make a motion to adopt the final preamble and regulations and send it on its merry way and that separately that we keep this part of the vortex that we have.

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1
   MS. GETZEY HART:
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                Second.
3
   MR. BARRETT:
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                For clarity of the record, the motion is
 5
                in reference to Regulation 16A-5433, the
                 Pharmacy Tech Registration Regulation.
 6
7
   VICE CHAIR ESTERBROOK:
                We have a motion and a second.
8
9
                discussion. We'll call to a vote.
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                Esterbrook, aye; Hart, aye; Slagle, aye;
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                Talbott, aye; Claggett, aye; Ritchie,
13
                aye; Roussel, aye.
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   [The motion carried unanimously.]
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   [Marc Farrell, Esquire, Regulatory Counsel, Office of
   Chief Counsel, Department of State, informed Board
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   members that they could do a standalone for the Act
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   77 items not being included. He noted the final
20
   annex and preamble will be available in about a month
21
   and a half once they are delivered to IRRC.
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        Ms. Talbott referred to the June minutes, noting
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   they did not have many substantive comments, but
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   there were some cleanups, including forms of
25
   identification and when someone has to file.
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Mr. Farrell noted that all of the comments are also available on IRRC's website at irrc.state.pa.us. He explained that they could do a final-omitted package for the Act 77 items and have that start at the beginning of the year when they come back in session.

Mr. Barrett also mentioned they could tie that in since they are going to talk about it in the general revisions to just have a broader record of Board discussion.

Ms. Talbott commented that the Board invites everybody to regulatory work sessions in the beginning, so there are not many changes later to the package to slow down the process.

Mr. Farrell asked whether Board members wanted to defer the first part of the general revisions, and Ms. Talbott suggested October 2024.

Chair Roussel stated it is reasonable to do the automation section in October 2024. She asked how they would inform the public in advance and whether they wanted to line up § 27.21 through § 27.27 for December to get that out as well. She noted they could share general version's part 2 concerning technology and automation § 27.201 through § 27.206 and discuss that at the October 2024 meeting.

Mr. Farrell offered to work with Dr. Trimmer to send out the information and descriptions for the upcoming agenda.

Chair Roussel again stated she would like to have a discussion regarding § 27.21 through § 27.27 in December and possibly getting through § 27.42 because the next sections are renewal of licensure and then institution regulations, which is qualified institutions, and institutional regulation at § 27.42.

Mr. Farrell asked UPMC whether the automation regulations that are in there now are exactly what they are looking at as far as needing updated or needing revised or whether they are looking to add something completely brand new that is not there now.

Dr. Taylor explained that the Board's regulations do not address what they are requesting and referred to the comment regarding different states, where they did it through a waiver for 30 years in Ohio before they wrote it in the regulations. She mentioned that the regulations need an update because it has been 14 years.

Mr. Maloney stated he would review the automation section. The language as discussed was already in the regulations in the delegation section and suggested a transfer of that into the automation.

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Chair Roussel believed the Board addressed that
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   in the regulation written in March 2024, noting they
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   have access to the Model Act from the National
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   Association of Boards of Pharmacy (NABP) website.
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        Mr. Farrell offered to provide part 2 to
   stakeholders, noting it has other sections in
6
7
   automation that may need touched to give them the
8
   full context.
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   Adjournment
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   VICE CHAIR ESTERBROOK:
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                 Motion to adjourn.
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   MS. TALBOTT:
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                 So moved.
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   MS. GETZEY HART:
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                 Second.
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   [There being no further business, the State Board of
   Pharmacy Meeting adjourned at 11:36 a.m.]
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CERTIFICATE

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

hom Dui

Lauren Gusherowski,

Minute Clerk

Sargent's Court Reporting Service, Inc.