State Board of Pharmacy May 2, 2023

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BOARD MEMBERS:

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General

13 14 Patrick M. Greene, Esquire, Office of Attorney

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48 49 50 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. - Absent

BUREAU PERSONNEL:

Carole Clarke Smith, Esquire, Senior Board Counsel Ariel O'Malley, Esquire, Board Counsel Ray J. Michalowski, Esquire, Senior Board Prosecutor Alice R. Glasser, Esquire, Board Prosecution Liaison Glenn P. Masser, Esquire, Board Prosecutor Caroline A. Bailey, Esquire, Board Prosecutor Ashley P. Murphy, Esquire, Board Prosecutor Nicole L. VanOrder, Esquire, Board Prosecutor Melanie Zimmerman, R.Ph., Board Administrator Marc Farrell, Esquire, Regulatory Counsel, Office of Chief Counsel, Department of State Andrew LaFratte, MPA, Executive Policy Specialist, Department of State Jessica Zukoski, Senior Legal Analyst, Department of State Michael Foerster, Hearing Examiner, Department of

ALSO PRESENT:

State

Timothy Black, R.Ph., Pharmacy Inspector, Bureau of Enforcement and Investigation, Department of State Catherine Lutz, Pharmacy Inspector, Bureau of Enforcement and Investigation, Department of State Larry Jones, Executive Director, Pennsylvania Society of Health-System Pharmacists

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ALSO PRESENT: (cont.)

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Jim Reed, Health Outcomes Supervisor/Strategic Partnerships Leader, Walgreens
Charlotte Harris Pharmacy Intern Duguesne Uni

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

11 Jacquelyn Sassaman, Pentec Health

12 Judy Kutchman, AllianceRx Walgreens Prime 13 Steven Zahn, Pharmacy Inspector, Bureau of

Enforcement and Investigation, Department of State

15 Dylan Sleyo16 Joseph Brett

17 Laura Lenert

18 Matt

19 Andy Tang

20 Mary Tran, Pharm.D., Executive Fellow, Pennsylvania 21 Pharmacists Association

Jennifer Raibley, Division Pharmacy Manager, ACME Markets

Stacey Smilek, Director of Pharmacy, Wills Eye Hospital

Christine Renfer, Pharm.D., Director of Professional Practices & Pharmacist in Charge, CVS/Caremark Pharmacy

Nicole Kruczek RPh, MPBA, Lead Director, Pharmacy Operations, CVS Health

Leigh Shirley, Director of Pharmacy Operations, Giant Food Stores

Kimberly Mehta, Pharm.D., MPH, Director of Medication Safety and Regulatory, Allegheny Health Network

Christopher Miller, Pharm.D., Giant Eagle

Nicole Fidler, Associate, Malady & Wooten

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

Valerie Pentland, PharmD, ConnectiveRx

Kristofer Rivers, Clinical Supervisor, UPMC Pinnacle Robin Becker, Assistant Director, Pharmacy Operations at Thomas Jefferson University Hospitals

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

Grace Sesi, Executive Director, Regulatory Affairs at CVS Health/Chairperson, Michigan Board of Pharmacy Victoria Elliott, RPh, MBA, CAE, CEO, Pennsylvania Pharmacists Association

5 * * * 1 2 State Board of Pharmacy 3 May 2, 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 11 a.m.] 12 13 The regularly scheduled meeting of the State 14 Board of Pharmacy was held on Tuesday, May 2, 2023. 15 Theresa M. Talbott, R.Ph., Chairperson, called the 16 meeting to order at 10:31 a.m. 17 18 Pledge of Allegiance 19 [The Pledge of Allegiance was recited.] * * * 20 21 [Theresa M. Talbott, R.Ph., Chairperson, asked everybody to turn off their cell phones. She also 22 23 noted that the meeting was being recorded, and those 24 who continued to participate were giving their 25 consent to be recorded.]

6 1 Evacuation Announcement 2 3 [Melanie Zimmerman, R.Ph., Board Administrator, 4 reviewed the emergency evacuation procedures for One 5 Penn Center. 1 * * * 6 7 Introduction of the Board Members/Staff/Audience [Theresa M. Talbott, R.Ph., Chairperson, requested an introduction of Board members, Board staff and the 10 audience.1 11 12 Approval of Agenda 13 CHAIRPERSON TALBOTT: 14 We have two changes. Our 11 a.m. 15 appointment has canceled and Consent Agreements 11, 12, 13, and 14 have been 16 17 withdrawn. 18 I would entertain a motion to 19 approve the agenda as amended. 20 DR. ROUSSEL: 21 I make a motion to approve the agenda as 22 amended. 23 MR. SLAGLE: 24 Second. 25 CHAIRPERSON TALBOTT:

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Any other discussion? Call for a vote.
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                 Esterbrook, aye; Claggett, aye; Talbott,
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                 aye; Roussel, aye; Greene, aye; Slagle,
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                 aye.
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   [The motion carried unanimously.]
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   Approval of Minutes
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   CHAIRPERSON TALBOTT:
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                 Approval of minutes from March 21.
11
                     Do I have a motion to accept the
                 minutes?
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13
   DR. ROUSSEL:
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                 I make a motion to approve the minutes
15
                 from March 21, 2023.
16
   CHAIRPERSON HART:
17
                 Do I have a second?
18
   MR. SLAGLE:
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                 I'll second that.
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   CHAIRPERSON TALBOTT:
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                 Any discussion? Hearing none. Call the
22
                 vote.
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24
                 Esterbrook, aye; Claggett, abstain;
                 Talbott, aye; Roussel, aye; Greene, aye;
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8 1 Slagle, aye. 2 [The motion carried. Arion Claggett abstained from 3 voting on the motion.] 4 5 Report of Board Prosecution 6 [Caroline A. Bailey, Esquire, Board Prosecutor, 7 presented the Consent Agreements for Case No. 19-54-017836, Case Nos. 22-54-005324 & 22-54-005326, and Case Nos. 22-54-011259 & 22-54-017129.] 10 11 [Theresa M. Talbott, R.Ph., Chairperson, exited the 12 meeting at 10:42 a.m. for recusal purposes.] 13 * * * 14 [Glenn P. Masser, Esquire, Board Prosecutor, 15 presented the Consent Agreement for Case No. 22-54-16 007567.1 * * * 17 18 [Theresa M. Talbott, R.Ph., Chairperson, reentered 19 the meeting at 10:44 a.m.]

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21 [Glenn P. Masser, Esquire, Board Prosecutor,

22 presented the Consent Agreement for Case No. 22-54-

23 014878.]

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25 [Alice R. Glasser, Esquire, Board Prosecution

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Liaison, presented the Consent Agreements for Case
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2
   No. 21-54-019152 and Case Nos. 22-54-004725 & 22-54-
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   004726.1
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   [Ray J. Michalowski, Esquire, Senior Board
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   Prosecutor, informed Board members that the withdrawn
7
   cases at items 11 through 14 would be prepared and on
   the agenda for the next meeting.]
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   Report of Board Counsel - Regulatory Report
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   [Ariel E. O'Malley, Esquire, Board Counsel, noted no
12
   regulatory changes since the last meeting.
13
   stated there would be a general revisions work
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   session toward the end of the meeting to review the
15
   annex for general revisions. She mentioned the Board
16
   would probably be making a motion for an exposure
17
   draft at the next meeting.]
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   Report of Board Counsel - Legislative Report
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   [Ariel E. O'Malley, Esquire, Board Counsel, referred
21
   to Senate Bill 81 regarding emergency medical
22
   services (EMS) and their ability to dispense
23
   naloxone. She noted it has been amended and removes
24
   the insurance provision and believed it is with the
25
   Appropriations Committee.
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Ms. O'Malley stated the House Bill 758 was introduced and would require the Pennsylvania Human Relations Commission to develop and pharmacists complete online training every 2 years to understand and mitigate social bias, which could be considered toward continuing education.

Ms. O'Malley stated House Bill 817 and House Bill 818 go together. She noted House Bill 817 would amend the Pharmacy Act to require the Board to educate pharmacies as to how they could modify Drug Enforcement Administration (DEA) registration to receive and destroy mail back packages and to install, manage, and maintain collection receptacles.

Ms. O'Malley noted it would also require the Board to recommend pharmacies to modify their registration and was introduced and referred to the Committee on Health on April 3, 2023.

Ms. O'Malley stated House Bill 818 would provide \$2 million to the Department of State to administer that educational program and support the Board's efforts to provide that educational program.]

* * *

24 Report of Board Counsel - Matters for Deliberation 25 [Ariel E. O'Malley, Esquire, Board Counsel, referred

to item 18, noting it is a case where there has been 1 2 an order to show cause and an answer filed. 3 noted the Board deliberated in Executive Session but 4 would not be delegating that, so there would not be a 5 vote later in the meeting. She mentioned there would 6 be a motion and a vote for item 19 during the 7 meeting.] * * * 8 9 Report of Board Counsel - Miscellaneous Items 10 [Ariel E. O'Malley, Esquire, Board Counsel, stated 11 item 21 would also be a vote later during the 12 meeting. She referred to the DEA training for the 13 Board's information, noting training is due June 27. 14 15 Ms. O'Malley also provided Recusal Guidelines for 16 the Board's information. 17 Dr. Roussel asked Mr. Michalowski to explain the 18 relationship between the Food and Drug 19 Administration's (FDA) Section 503B compounding 20 facility action and the Board of Pharmacy. She noted 21 there is a memorandum of understanding (MOU) from the 22 FDA requesting boards inform the FDA within a certain

25 because they usually cannot discuss investigations

period of time of an ongoing investigation.

mentioned that many states cannot sign the MOU

23

1 until they are closed and requested more information.

Dr. Roussel also asked whether communication would be provided to the Board if the FDA opens an investigation on a 503B pharmacy in the state of Pennsylvania.

Mr. Michalowski explained that the MOU has not been signed in Pennsylvania and not been raised by the FDA in 6 months to a year. He noted they have an investigative MOU with the FDA that is related to all sorts of cases. He mentioned that there used to be a meeting with the FDA yearly, along with the Department of Health. He reported other states have adopted language dealing with 503B and 503A regarding pharmacies and outsourcing facilities but Pennsylvania has not.

Mr. Michalowski explained that the FDA notified them of a 503B investigation or inspection in the past and also invited the pharmacy inspector in that region. He stated staff from the National Association of Boards of Pharmacy (NABP) Verified Pharmacy Program (VPP) did that as well, noting their inspectors would co-inspect at the same time. He mentioned that those meetings are not held any longer due to the lack of staff in the Philadelphia office

and have not reinstituted the regular annual check with prosecution.

Mr. Michalowski informed Board members that they receive occasional information but not as often as before. He mentioned that the FDA has been involved in a case where prosecution found an unexpected compounding facility in the pharmacy that was never on the pharmacy blueprint. He noted prosecution does reach out but communication is not what it had been in the past.

Mr. Michalowski stated 503A and 503B were very hot in the news and very controversial at the time but the industry has settled in more at this point. He noted checking the website where they maintain all of their inspections, especially if they receive a complaint related to compounding to see if there has been a recent inspection or warning letter. He mentioned that they are not informing prosecution of them consistently or there are not as many.]

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21 Report of Board Chairperson

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22 | [Theresa M. Talbott, R.Ph., Chairperson, informed

23 Board members that she provided a continuing

24 education (CE) Board update at the Duquesne

25 University Alumni Association Meeting on April 15.

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She noted everyone gasped when they saw the slide of
the regulatory process but understand the Board is
not at fault for the lengthy process.
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Chair Talbott mentioned that she would be attending the National Association of Boards of Pharmacy Meeting next week in Nashville, along with other Board Members. She noted they would not be discussing any Board business at that time but would be raising the Pennsylvania flag proudly.]

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11 Report of Acting Commissioner - No Report

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13 Report of Board Administrator

14 [Theresa M. Talbott, R.Ph., Chairperson, asked whether they were still utilizing a schedule of

16 roughly 60 days until they release the applications

17 for pharmacy and nonresident pharmacy renewals.

Ms. Zimmerman explained that the goal is 60 days before the expiration date, which should be around

20 July 1.]

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22 Discussion Items

23 | [Theresa M. Talbott, R.Ph., Chairperson, noted the

24 | Board reviewed the NABP District 2 Well-Being Index

25 and the proposed amendments to NABP Constitution and

Bylaws and would be voting on those proposed amendments at the NABP Annual Meeting next week.

Dr. Roussel also mentioned the proposal that someone appointed to a task force or committee through NABP but would timeout of their appointment for the prospective board of pharmacy for the state they are representing would be allowed to continue to serve for that task force until the end of their term appointment to the task force.

Chair Talbott noted that motions would be made concerning the three licenses at items 26 through 28 later in the meeting.]

14 FYI Items

[Theresa M. Talbott, R.Ph., Chairperson, announced the Food and Drug Administration is having a virtual public meeting May 10-11 on opioid use disorder treatment and is free to the public. She mentioned that the information could be found on the FDA's website. She encouraged everyone to keep an eye on NABP's website for comments on DEA's proposed regulations regarding telemedicine.

Chair Talbott noted prior discussion regarding volunteering for NABP's 2023-2024 committees and task forces.]

16 1 2 MOTIONS 3 CHAIRPERSON TALBOTT: 4 The Board of Pharmacy met in Executive 5 Session earlier today to conduct quasijudicial deliberations and receive 6 7 quidance from Ariel. Are there any motions that came from 8 9 that session? 10 MR. GREENE: 11 At agenda item 4, I make a motion that we 12 approve the Consent Agreement at Case No. 13 19-54-017836. 14 DR. ROUSSEL: 15 I second the motion. 16 CHAIRPERSON TALBOTT: 17 Any discussion? Call the vote. 18 19 Slagle, aye; Greene, aye; Roussel, aye; 20 Talbott, aye; Esterbrook, aye; Claggett, 21 abstain. 22 [The motion carried. Arion Claggett abstained from 23 voting on the motion. The Respondent's name is 24 EdPharma LLC.] 25 * * *

17 1 MR. GREENE: 2 At agenda item 5, I make a motion that we 3 approve the Consent Agreement at Case Nos. 22-54-005324 & 22-54-005326. 4 DR. ROUSSEL: 5 Second. 6 7 CHAIRPERSON TALBOTT: 8 Any discussion? Call the vote. 9 10 Slagle, aye; Greene, aye; Roussel, aye; Talbott, aye; Claggett, abstain; 11 12 Esterbrook, aye. 13 [The motion carried. Arion Claggett abstained from 14 voting on the motion. The Respondents are Patient 15 Care Pharmacy & Alex N. Luong, R.Ph.] 16 MR. GREENE: 17 18 At agenda item 6, I make a motion that we 19 approve the Consent Agreement at Case 20 Nos. 22-54-011259 & 22-54-017129. 21 DR. ROUSSEL: 22 I second that motion. 23 CHAIRPERSON TALBOTT: 24 Any discussion? Call the vote. 25

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                Slagle, aye; Greene, aye; Roussel, aye;
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                 Talbott, aye; Claggett, abstain;
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                Esterbrook, aye.
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   [The motion carried. Arion Claggett abstained from
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   voting on the motion. The Respondents are Lebanon
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   Shops Pharmacy & Thomas Clark Riley, R.Ph.]
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                              * * *
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   MR. GREENE:
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                At agenda item 7, I make a motion that we
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                reject as too lenient the Consent
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                Agreement at Case No. 22-54-007567.
   DR. ROUSSEL:
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13
                Second.
14
   CHAIRPERSON TALBOTT:
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                Any discussion? Call the vote.
16
                 Slagle, aye; Greene, aye; Roussel, aye;
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18
                 Talbott, recuse; Claggett, abstain;
19
                Esterbrook, aye.
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   [The motion carried. Theresa Talbott recused herself
21
   from deliberations and voting on the motion. Arion
22
   Claggett abstained from voting on the motion.]
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24
   MR. GREENE:
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                At agenda item 8, I make a motion that we
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19 1 approve the Consent Agreement at Case No. 22-54-014878. 2 3 DR. ROUSSEL: 4 Second. 5 CHAIRPERSON TALBOTT: Any discussion? Call the vote. 6 7 Slagle, aye; Greene, aye; Roussel, aye; 9 Talbott, aye; Claggett, abstain; 10 Esterbrook, aye. 11 [The motion carried. Arion Claggett abstained from 12 voting on the motion. The Respondent's name is Joan 13 M. Sullivan.] * * * 14 15 MR. GREENE: 16 At agenda item 9, I make a motion that we 17 approve the Consent Agreement at Case No. 18 21-54-019152. DR. ROUSSEL: 19 20 Second. 21 CHAIRPERSON TALBOTT: 22 Any discussion? Call the vote. 23 24 Slagle, aye; Greene, aye; Roussel, aye; 25 Talbott, aye; Claggett, aye; Esterbrook,

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20
1
                 aye.
2
   [The motion carried unanimously. The Respondent's
3
   name is Archway Apothecary.]
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   MR. GREENE:
                 At agenda item 10, I make a motion that
6
7
                 we approve the Consent Agreement at Case
                 Nos. 22-54-004725 & 22-54-004726.
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9
   DR. ROUSSEL:
10
                 Second.
11
   CHAIRPERSON TALBOTT:
12
                 Any discussion? Call the vote.
13
14
                 Slagle, aye; Greene, aye; Roussel, aye;
15
                 Talbott, aye; Claggett, aye; Esterbrook,
16
                 aye.
17
   [The motion carried unanimously. The Respondents are
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   Kevin Hennessy & The Compounding Pharmacist.]
                              * * *
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   MR. GREENE:
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                 At agenda item 19 in the matter of Nola
22
                 Mini Market, LLC, I make a motion that we
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                 delegate the matter to a hearing examiner
24
                 for a hearing.
25
   DR. ROUSSEL:
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21 I second the motion. 1 2 CHAIRPERSON TALBOTT: 3 Any discussion? Call the vote. 4 5 Slagle, aye; Greene, aye; Roussel, aye; Talbott, aye; Claggett, aye; Esterbrook, 6 7 aye. [The motion carried unanimously.] 8 9 10 MR. GREENE: 11 At agenda item 20 in the matter of BPOA 12 v. Central Admixture Pharmacy Services, 13 Inc., I make a motion that we approve the 14 Proposed Adjudication and Order. 15 DR. ROUSSEL: 16 Second. 17 CHAIRPERSON TALBOTT: 18 Any discussion? Call the vote. 19 20 Slagle, aye; Greene, aye; Roussel, aye; 21 Talbott, aye; Claggett, aye; Esterbrook, 22 aye. 23 [The motion carried unanimously.] 24 * * * 25 MR. GREENE:

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23
   [The motion carried unanimously.]
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   MR. GREENE:
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                 At agenda item 27, I make a motion that
5
                 we deny the Application of Kazim Oyenuga.
6
   DR. ROUSSEL:
7
                 Second.
8
   CHAIRPERSON TALBOTT:
9
                 Any discussion? Call the vote.
10
11
                 Esterbrook, aye; Claggett, aye; Talbott,
12
                 aye; Roussel, aye; Greene, aye; Slagle,
13
                 aye.
14
    [The motion carried unanimously.]
15
   MR. GREENE:
16
                 At agenda item 28, I make a motion that
17
18
                 we provisionally deny the Nonresident
19
                 Pharmacy Application of Musely
20
                 Compounding Pharmacy LLC.
21
   DR. ROUSSEL:
22
                 Second.
23
   CHAIRPERSON TALBOTT:
24
                 Any discussion? Call the vote.
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1
                Esterbrook, aye; Claggett, aye; Talbott,
2
                aye; Roussel, aye; Greene, aye; Slagle,
3
                aye.
4
   [The motion carried unanimously.]
                              * * *
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6
   [The Board recessed from 11:06 a.m. until 11:15 a.m.]
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8
   Appointment - Pennsylvania Insurance Department -
9
     Pennie Health Insurance Presentation
10
   [Charles (Chachi) Angelo, Director of External
11
   Affairs, Pennie, stated Pennie was established from
12
   unanimous bipartisan legislation passed in July 2019
13
   for Pennsylvania to move away from HealthCare.gov.
14
   He noted the money being sent to Healthcare.gov set
15
   up two programs at the same cost by setting up the
16
   exchange and a reinsurance program to increase
17
   premium savings for middle income families.
18
        Mr. Angelo explained that Pennie aims to maximize
19
   the number of Pennsylvanians with affordable quality
20
   health coverage and facilitate informed consumer
21
   decision-making.
22
        Mr. Angelo mentioned that Pennie is the official
23
   health insurance marketplace for Pennsylvania for
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high-quality, affordable health insurance plans that

could be purchased off of the exchange. He explained

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that Pennie helps reduce the cost of monthly payments through tax credits and cost-sharing reductions.

Mr. Angelo stated Pennie helps individuals and families who do not have coverage through their employer, the uninsured, and Medicaid population. He explained that they operate a no wrong door policy for everyone to receive the right coverage. He noted the third open enrollment ended in mid-January with over 371,000 customers enrolled with about 90 percent eligible for tax credits.

Mr. Angelo addressed financial assistance, where the advanced premium tax credit is an immediate tax credit and cost-sharing reductions help with copays, deductibles, and coinsurance. He mentioned that the American Rescue Plan and the Inflation Reduction Act increased the amount of financial savings someone could receive.

Mr. Angelo noted that plans are available in bronze, silver, and gold starting at zero cost for those who qualify. He reported that early retirees around age 55 to 64 and are 36 percent of Pennie customers because they are not working but are not available for Medicare.

Mr. Angelo addressed the enrollment period starting November 1 to January 15, along with a

special enrollment period that runs throughout the
year for a qualifying life event. He noted a special
enrollment period opens automatically for someone
whose income falls below or at 150 percent of the
federal poverty level.

Mr. Angelo discussed a new program in collaboration with the Department of Revenue called the Path to Pennie that helps connect uninsured Pennsylvania tax filers with information about Pennie and then Pennie provides an estimate of how much financial assistance could be applied to a health plan.

Mr. Angelo addressed changes to Medicaid, noting it to be a big initiative from the Department of Human Services (DHS), Pennie, Children's Health Insurance Program (CHIP), and state government as a whole. He explained that the Medicaid continuous coverage requirement during the public health emergency did not allow anyone to be disenrolled even if their income changed.

Mr. Angelo stated the continuous coverage requirement was uncoupled from the public health emergency in December 2022, where those receiving Medicare would be required to fill out a renewal packet for proper redetermination. He mentioned that

DHS started determining eligibility in April, noting that no one would lose coverage without proper notification and chance to renew.

Mr. Angelo expressed the importance of everyone being aware of Pennie and that coverage is more affordable than ever. He mentioned that there are several links to access some of the cobranded materials from DHS, Pennie, managed care organizations (MCOs), and qualified health plan (QHP) insurers.

Mr. Angelo stated Pennie made health insurance purchasing easier by providing customer service with Pennie-certified assistors and Pennie-certified brokers in every county, along with having countless tools that are available at pennie.com. He encouraged everyone in the pharmacy profession to provide information about pennie.com or COMPASS to those without health insurance and he provided links to web sites.

Mr. Angelo offered to have someone from the Pennie team to provide virtual or in-person Pennie education sessions. He mentioned that DHS and Pennie began advertising in hopes of getting the word out.

Mr. Angelo addressed policy changes for individuals being transitioned over to Pennie from

- 1 | Medical Assistance, which now includes a 120-day
- 2 | special enrollment period for loss of Medicaid,
- 3 | Medical Assistance, or CHIP but encouraged
- 4 | individuals to enroll within 60 days to avoid a gap
- 5 in coverage.
- 6 Chair Talbott commented that Pennie is one of the
- 7 best seen across the country and thanked Mr. Angelo
- 8 and his team for their work. She encouraged all of
- 9 the pharmacy associations to get the information out
- 10 to members.
- 11 Scott Yeager, Outreach Manager, Pennie, provided
- 12 contact information in the chat feature of the Teams
- 13 meeting and offered to answer any additional
- 14 questions.
- 15 Patrick Lavella, R.Ph., President, Pennsylvania
- 16 | Pharmacists Association, commented that the pharmacy
- 17 | profession would like to help patients, but they are
- 18 eliminated from some of those plans, noting less than
- 19 | 40 pharmacies in the state have been accepted into
- 20 that marketplace plan with one of their payers and
- 21 asked Mr. Angelo for his contact information because
- 22 | the Pennsylvania Insurance Department referred him to
- 23 Pennie.
- 24 Chair Talbott again thanked Mr. Angelo and Mr.
- 25 Yeager for the work they do for their patients.]

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2 Regulatory Work Session

3 [Theresa M. Talbott, R.Ph., Chairperson, informed

4 everyone that the Board would be reviewing the first

5 | 15 pages of the 35-page general revisions packet.

6 | She noted the definition of long-term care facility

7 under § 27.1 to now include hospice, assisted living,

8 personal care home, correctional facility, and

9 juvenile detention facility.

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Chair Talbott noted pharmacist manager was changed to pharmacist in charge throughout the regulations. She stated § 27.11(b) clarified pharmacy relationships, noting the requirement was waived 4 years ago to allow a pharmacy that has a legal or contractual right to use an affiliated name.

Chair Talbott addressed § 27.11(d) regarding a change in the name of a pharmacy, where they are required to submit a name change on a form within 30 days and would have to satisfy requirements if there is a change in ownership. The Board is waiting on information from Delaware, and Chair Talbott suggested leaving it as is for now.

Chair Talbott addressed § 27.11(g) regarding the pharmacist in charge, noting it used to be within 15 days and then a pharmacy could apply for another 30-

day waiver to replace the pharmacist manager. She noted the pharmacist manager replacement requirement must be done within 30 days of the change and then if a new pharmacist cannot be found, a request for an additional 15 days may be placed. She mentioned the clarification, where a pharmacist in charge does not leave the position but would be away from the pharmacy for more than 30 days that the pharmacy must change the pharmacist in charge.

Chair Talbott referred to delegation of duties under § 27.12(b)(1), noting it was cleaned up to reflect the technician bill, where direct and immediate personal supervision to pharmacy interns means the supervisor pharmacist has reviewed the order prior to being dispensed, has verified the final product, and is immediately available on the premises through in person or real time electronic means, can direct the work of interns and technicians, and respond to questions and problems.

Chair Talbott mentioned that the "comma" was replaced with "and" under § 27.12(c) for pharmacy interns and the same for technicians under (d). She noted pharmacists in charge under § 27.12(d)(4) shall create and maintain a written protocol for each technician employed by the pharmacy, protocol shall

specify each duty which the technician may perform, and the pharmacist in charge and the technician shall sign and date it.

Chair Talbott stated remote data entry was lifted out of the tech bill and placed at Board Regulation Section 27.12(e).

Chair Talbott noted § 27.14(c)(2) spells out prescription files in electronic or hard copy format.

-The new § 27.14(c)(4) specifies an electronic or hard copy reference library is acceptable as long as there is immediate access.

Chair Talbott referred to Standards of Practice under § 27.18(d) regarding the container, where they are adding registered name (or derivation thereof as approved by the Board) and, if applicable, the DEA number of the pharmacy. She noted the change in language to "prescription number" because they are not called serial numbers anymore and the date that either it was originally filled and/or the date the prescription was most recently filled, where one or the other is acceptable. She noted it would also have the trade or brand name using abbreviations if necessary and then the name of the manufacturer if the drug is generic using abbreviations if necessary.

Chair Talbott addressed § 27.18(h), if a

- 1 prescriber dies, the prescription could be refilled
- 2 for up to 90 days from when the prescriber died but
- 3 | pharmacists cannot refill controlled substance
- 4 prescriptions. She noted the word active would be
- 5 added to § 27.18(h)(3) to read "Active On
- 6 probation."
- 7 Chair Talbott addressed prescriptions for
- 8 | Schedule II, where prescriptions for Schedule II may
- 9 be partially filled because of the Controlled
- 10 Substances Act relating to partially filled
- 11 prescriptions or other applicable state and federal
- 12 laws in case they change something. She stated
- 13 | Schedule III and IV may not be refilled more than
- 14 | five times; and prescriptions for III, IV, and V may
- 15 be partially filled as authorized by the federal
- 16 | Controlled Substances Act or other applicable federal
- 17 and state law.
- 18 Chair Talbott mentioned prior discussion
- 19 regarding the addition of (u) under Standards of
- 20 Practice. She mentioned that options A, B, and C are
- 21 available but preferred option (B), if you violate
- 22 any other applicable federal law or law of the
- 23 commonwealth including, but not limited to, the
- 24 | federal Controlled Substances Act, the Controlled
- 25 | Substance, Drug, Device, and Cosmetic Act, or the

rules and regulations promulgated thereunder; and a violation of such constitutes a violation of this chapter and the act.

Chair Talbott referred to option A, which is what the regulation currently has and reads, a violation by a pharmacist of the federal Controlled Substances Act, the Controlled Substance, Drug, Device, and Cosmetic Act, or the rules and regulations promulgated thereunder constitutes a violation of this chapter and the act. She mentioned the addition of pharmacists and pharmacies shall comply with any other applicable federal laws and/or laws of this commonwealth and or regulations, and a violation of such constitutes a violation of this chapter andthe act.

Chair Talbott stated option B splits that last sentence, where pharmacists and pharmacies shall comply with any other applicable federal laws and laws of the commonwealth and/or regulations including, but not limited to, and then it keeps the federal citations and a violation of such constitutes a violation of this chapter and the act.

Chair Talbott mentioned they could just add a section (V) to read, a violation by a pharmacist or pharmacy of any other applicable federal laws and/or

laws of this commonwealth and/or regulation shall constitute a violation of this chapter and of the act.

Ms. O'Malley reminded Board members of prior discussion at the last meeting to add language so prosecution would have the ability to more cleanly and clearly charge this in their orders to show cause and in consent agreements.

Mr. Michalowski stated the legislation is making standalone bills instead of incorporating things into the Pharmacy Act for opiate prescribing, Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP), and the one discussed today because they often go into the Drug Act and do not go into the Pharmacy Act and become nebulous.

Mr. Michalowski suggested changing the language in option B from "any other" to "all," which is also the option prosecution favored as well.

Chair Talbott noted the Board chose option B, where pharmacist and pharmacies shall comply with all other applicable federal laws and/or laws of the commonwealth and/or regulations.

Chair Talbott referred to prospective drug review and patient counseling under § 27.19, where nursing home was changed to long-term care facility. She

also referred to offer to counsel under § 27.19(d), where they are cleaning up how the offer was made to counsel to read, pharmacist or designee shall make the offer to counsel in person if a patient or caregiver is in the pharmacy and opening it up to read, written offer to counsel must include the telephone of the pharmacy or other means of communicating.

Chair Talbott noted an intern may only counsel under the direction of a pharmacist under the intern section. She also noted if a patient or caregiver indicates that they want counseling, then the pharmacist shall do it in person.

Chair Talbott addressed facsimile machines under \$ 27.20, where a pharmacist may fill and dispense a valid prescription for a Schedule III, IV, or V received on a facsimile machine. She noted the DEA changed what constitutes a valid prescription, and if they change it again, the Board would not have to go back and change it.

Chair Talbott addressed a change in pharmacy internship under § 27.26, which will codify the waiver from 2018, so that an intern may earn the 1500 hours in an internship program sponsored or approved by an Accreditation Council for Pharmacy Education

(ACPE) ACPE-accredited pharmacy degree program.

Chair Talbott addressed biennial renewal under \$ 27.31 to remove language referring to the form being mailed to the holder and replacing it with a form being provided by the Board in advance of the renewal period or completion of an online electronic form and payment of a fee. She noted licenses must renew every 2 years and attest to continuing education requirements.

Chair Talbott noted compliance could be proved under § 27.32(a) continuing education by attesting to completion and submitting a form provided to the pharmacist by the Board. Pharmacists can demonstrate compliance with subsection (a) by submitting a CPE monitor or activity record from the pharmacist NABP's profile. She noted the word "certificates" would be changed to "records."

Chair Talbott addressed graduates of foreign schools and noncitizens under § 27.52, where ACPE was changed to Accreditation Council for Pharmacy Education throughout.

Ms. O'Malley noted that graduates of pharmacy schools which are not ACPE-accredited must achieve Foreign Graduate Pharmacy Examination Committee certification before applying for a pharmacy intern

registration or a pharmacist license and provide such documentation to the Board.

Ms. Zimmerman explained that the Board requires information to come directly from NABP and suggested rephrasing the language because it is not the applicant providing the information. She further explained that information is pulled directly from NABP's website. The Board agreed to remove "and provide such documentation to the Board."

Mr. Michalowski referred to § 27.32(b) under continuing education and suggested changing the word "prove" in the first sentence to "shall demonstrate compliance" to be consistent.

Ms. O'Malley addressed electronically transmitted prescriptions under § 27.201 and prior discussion whether or not to put Act 96 under a separate regulation.

Chair Talbott noted electronically transmitted prescription means communication of a prescription or refill by electronic means on a secure network and the term does not include a prescription refill authorization transmitted orally by phone or by fax and brings them into federal law compliance. It also has to be electronically encrypted or transmitted in full compliance with the Health Insurance Portability

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1 | Accountability Act (HIPAA) security standards. She
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- 2 | noted it is valid prescription provided transmission
- 3 complies with this chapter and other requirements of
- 4 federal state laws or regulations.
- 5 Chair Talbott addressed computerized
- 6 recordkeeping systems under § 27.202, where they need
- 7 to have traceability and who is responsible for
- 8 information entered into the pharmacy system by a
- 9 pharmacist or intern or tech under the supervision of
- 10 | the pharmacist.
- 11 Chair Talbott stated the Board would be voting on
- 12 the regulations on June 27 as an exposure draft and
- 13 then the regulations would be sent out for
- 14 distribution sometime before the fall.]
- 15
- 16 Adjournment
- 17 CHAIRPERSON TALBOTT:
- I entertain a motion to adjourn.
- 19 MR. ESTERBROOK:
- 20 Motion to adjourn.
- 21 CHAIRPERSON TALBOTT:
- 22 Second?
- 23 DR. ROUSSEL:
- 24 Second.
- 25 CHAIRPERSON TALBOTT:

All in favor? [The motion carried unanimously.] [There being no further business, the State Board of Pharmacy Meeting adjourned at 12:10 p.m.] 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. Derek Richmond, Minute Clerk Sargent's Court Reporting Service, Inc.

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		May 2, 2023	
	TIME	AGENDA	
	9:00	Executive Session	
	10:30	Return to Open Session	
	10:31	Official Call to Order	
	10:31	Pledge of Allegiance	
	10:32	<pre>Introduction of Board Members/Board Staff/Audience</pre>	
	10:35	Approval of Agenda	
	10:35	Approval of Minutes	
	10:36	Report of Board Prosecution	
	10:48	Report of Board Counsel	
	10:55	Report of Board Chairperson	
	10:56	Report of Board Administrator	
	10:57	Discussion Items	
	10:58	FYI Items	
	10:59	Motions	
	11:06	Recess	
	11:15	Return to Open Session	
	11:15	Appointment - Pennsylvania Department Insurance Presentation	of
	11:32	Regulatory Work Session	
	12:10	Adjournment	