1	COMMONWEALTH OF PENNSYLVANIA
2	DEPARTMENT OF STATE
3	BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
4	
5	<u>FINAL MINUTES</u>
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7	MEETING OF:
8	
9	STATE BOARD OF PHARMACY
10	
11	TIME: 10:30 A.M.
12	
13	Held at
14	PENNSYLVANIA DEPARTMENT OF STATE
15	2525 North 7th Street
16	CoPA HUB, Eaton Conference Room
17	Harrisburg, Pennsylvania 17110
18	as well as
19	VIA MICROSOFT TEAMS
20	
21	March 19, 2024
22	
23	
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25	

1 State Board of Pharmacy 2 March 19, 2024 3 4 5 BOARD MEMBERS: 6 7 Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson Arion R. Claggett, Acting Commissioner, Bureau of Professional and Occupational Affairs 8 9 10 Eric Esterbrook, R.Ph., Vice Chairperson 11 Janet Getzey Hart, R.Ph., Secretary 12 John R. Slagle, R.Ph. 13 Tyler Ritchie, Esquire, Deputy Attorney General, 14 Office of Attorney General 15 Theresa M. Talbott, R.Ph. 16 17 18 BUREAU PERSONNEL: 19 20 Carole Clarke Smith, Esquire, Senior Board Counsel 21 Ariel O'Malley, Esquire, Board Counsel 22 Tyesha C. Miley, Esquire, Board Counsel 23 Ray J. Michalowski, Esquire, Senior Board Prosecutor 24 Nathan C. Giunta, Esquire, Board Prosecution Liaison 25 Glenn P. Masser, Esquire, Board Prosecutor 26 Ashley P. Murphy, Esquire, Board Prosecutor 27 Christina Townley, Interim Board Administrator 28 Marc Farrell, Esquire, Regulatory Counsel, 29 Office of Chief Counsel, Department of State 30 Andrew LaFratte, MPA, Deputy Policy Director, Department of State 31 32 Jessica Zukoski, Senior Legal Analyst, Department of 33 State 34 35 36 ALSO PRESENT: 37 38 Kanda Patel, Pennsylvania Pharmacists Association, 39 Advanced Pharmacy Practice Experiential Student 40 Victoria Elliott, RPh, MBA, CAE, CEO, Pennsylvania 41 Pharmacists Association 42 Taylor Legette, Pharm.D., Postdoctoral Fellow, 43 Pennsylvania Pharmacists Association 44 Tiffany Booher, MA, LPC, CAADC, CIP, CCSM, Director, 45 Peer Assistance Monitoring Programs; Program 46 Director, Physicians' Health Program, Pennsylvania 47 Medical Society 48 Geoffrey Christ, Senior Pharmacy Compliance Manager, 49 Chewy Pharmacy 50

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	State Board of Pharmacy	
	March 19, 2024	
ļ	ALSO PRESENT: (cont.)	
	Larry Jones, Executive Director, Pennsylvania	
	Society of Health-System Pharmacists	
(	Genevieve Levans, R.Ph., Hospital of the University	
	of Pennsylvania	
	Nicole Fidler, Associate, Malady & Wooten	п
	Lauren McKenzie, Regional Pharmacy Manager, The GIANI Company	L
N	Veal Watson, Member Relations and Government Affairs	
	Director, National Association of Boards of	
	Pharmacy	
	Erin R. Kawa, Principal, Commercial Litigation, Regulatory & Administrative Agency Law, and	
	Professional Licensure Practice Groups, Post &	
	Schell	
3	hada Ayad, Pharm.D., Adjunct Faculty, St. Joseph's	
~	University Philadelphia College of Pharmacy	
2	Steven Zahn, Pharmacy Inspector, Bureau of Enforcement and Investigation, Department of State	
V	Iisha Patel, M.D., Curriculum Education Assistant,	
	Geisinger Commonwealth School of Medicine	
	Sarah Everingham, MJ, CCEP, CPhT, Cardinal Health	
	Kaitlyn Moss /ictoria Y. Chen, Pharm.D., Penn Medicine	
	Grace Sesi, Executive Director, Regulatory Affairs at	_
	CVS Health/Chairperson, Michigan Board of Pharmacy	
	Joshua Finger, Pharm.D., Enclara Pharmacia	
	Loan Nguyen, Pharm.D. Laura Romeo, Pharmacist-in-Charge at ConnectiveRx,	
	Careform Pharmacy	
	Christopher Miller, Pharm.D., Giant Eagle	
	David Klinger, System Director, Operations	
	& Compliance, Geisinger Health System	
(	Charlotte Harris, Pharmacy Intern, Duquesne Universit Jessica Adams, Pharm.D., BCPS, AAHIVE, Scientific	УY
	Director, Infectious Diseases at Clinical Care	
	Options	
	Sara Trimmer, Pharm.D., Green Thumb Industries	
	Timothy Black, R.Ph., Pharmacy Inspector, Bureau of	
	Enforcement and Investigation, Department of State Laura Lenart, Pharm.D., Pharmacist Supervisor,	
	Vetsource	
į	Samantha Chessie, Policy Manager, Animal Policy	
	Group, LLC	

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1 2 3	State Board of Pharmacy March 19, 2024
4 5 6	ALSO PRESENT: (cont.)
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5 \* \* \* 1 2 State Board of Pharmacy 3 March 19, 2024 \* \* \* 4 5 [Pursuant to Section 708(a)(5) of the Sunshine Act, at 9:00 a.m., the Board entered into Executive 6 7 Session with Ariel E. O'Malley, Esquire, Board 8 Counsel, for the purpose of conducting quasi-judicial 9 deliberations and to receive the advice of Board 10 Counsel. The Board returned to open session at 11 10:30 a.m.] \* \* \* 12 13 The regularly scheduled meeting of the State 14 Board of Pharmacy was held on Tuesday, March 19, 15 2024. Christine Roussel, Pharm.D., BCOP, BCSCP, Chairperson, called the meeting to order at 16 10:30 a.m. 17 \* \* \* 18 Introduction of the Board Members/Audience Members 19 20 [Chair Roussel requested an introduction of Board 21 members and audience members.] \* \* \* 22 23 Approval of the Agenda 24 CHAIRPERSON ROUSSEL: 25 At this time, are there any motions to

1 make for approval of the current agenda? 2 MR. ESTERBROOK: 3 Motion to approve. 4 MS. GETZEY HART: 5 Second. CHAIRPERSON ROUSSEL: 6 7 Any discussion? We'll call the vote. 8 9 Esterbrook, aye; Claggett, aye; Ritchie, 10 aye; Talbott, aye; Hart, aye; Slagle, 11 aye; Roussel, aye. 12 [The motion carried unanimously.] \* \* \* 13 14 [Chair Roussel noted the meeting was being recorded, 15 and those who continued to participate were giving 16 their consent to be recorded.] \* \* \* 17 18 Approval of Minutes CHAIRPERSON ROUSSEL: 19 20 Any discussion on the minutes? Any edits 21 required? Otherwise, I will entertain 22 23 approval. 24 MR. ESTERBROOK: 25 Motion to approve minutes from February

7 1 6, 2024. 2 ACTING COMMISSIONER CLAGGETT: 3 Second. 4 CHAIRPERSON ROUSSEL: 5 Let's call the vote. 6 7 Esterbrook, aye; Roussel, aye; Claggett, 8 aye; Ritchie, aye; Talbott, aye; Hart, 9 aye; Slagle, aye. 10 [The motion carried unanimously.] \* \* \* 11 12 Report of Board Prosecution 13 [Ashley P. Murphy, Esquire, Board Prosecutor, 14 presented the Consent Agreement for Case No. 22-54-15 012817.1 \* \* \* 16 17 [Glenn P. Masser, Esquire, Board Prosecution Liaison, 18 presented the Consent Agreement for Case No. 23-54-19 008408. He informed Board members agenda item 5 had 20 been withdrawn by prosecution.] \* \* \* 21 22 [Nathan C. Giunta, Esquire, Board Prosecution 23 Liaison, presented the Consent Agreements for Case 24 No. 20-54-000737, Case No. 21-54-012717, Case No. 22-25 54-001657, and Case No. 23-54-017189.]

1 2 Report of Board Counsel - Regulatory Report 3 [Ariel E. O'Malley, Esquire, Board Counsel, informed 4 Board members that the pharmacy technician regulation 5 is finally moving forward and was published as proposed on March 2, 2024. She noted receiving 6 7 comments asking to change the grandfathering date and 8 advised that the Board cannot change the date of the 9 grandfathering period because it is part of the 10 statute that was passed.

8

Ms. O'Malley noted regulations are on the same path, but the pharm tech reg was moving forward. She stated the regulation will come back before the Board once they receive the rest of the comments and hoped to be able to publish it as final in the near future, noting the Board will finally be able to start registering pharmacy technicians.

18 Chair Roussel noted going through general 19 revisions last year for the first half of the 20 chapter, and the Board will be considering the 21 general revisions for the second half of the chapter 22 this coming year. She strongly recommended that 23 stakeholders and professional organizations review 24 those sections, along with the Model Practice Act and 25 other state regulations, and then submit suggested

language to the Board to assist the staff with being
more efficient in their regulatory work sessions.
She noted regulatory work sessions will be scheduled
to work on the second half.

5 Ms. Talbott asked whether Ms. O'Malley could send 6 the draft copy of the back half to stakeholders, and 7 Ms. O'Malley offered to circulate the second half of 8 the annex.

9 Ms. Talbott asked whether the Board was going 10 final-omitted with the COVID and flu update. Ms. 11 O'Malley noted Ms. Talbott to be correct, and it 12 would match the legislation that passed, which does 13 not match what is currently in their regulations.] \* \* \* 14 15 Report of Board Counsel - Legislative Report [Ariel E. O'Malley, Esquire, Board Counsel, noted the 16

17 Legislative Report is largely the same from the prior 18 meeting, with the addition of House Bill 2037, which 19 was introduced February 20, 2024, and referred to 20 Children and Youth. She stated the bill would 21 authorize pharmacists to administer injectable 22 medications, biologicals, and immunizations to 23 persons 3 years or older.

24 Ms. O'Malley mentioned that it was previously 18 25 and reduced to 5 for flu and COVID. She stated it

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would also allow pharm techs to do the reporting for 1 2 the immunizations and allow pharm techs with the 3 appropriate training and CPR certificate to do COVID 4 immunizations. 5 Ms. Talbott informed Ms. O'Mally that it was not just COVID vaccines for techs, noting it mirrored the 6 7 Public Readiness and Emergency Preparedness (PREP) Act. She mentioned that it called out COVID in one 8 9 section, but believed it to cover everything. 10 Ms. O'Malley offered to double check and report 11 back with Ms. Talbott.] \* \* \* 12 13 Report of Board Counsel - Matter for Deliberation 14 [Ariel E. O'Malley, Esquire, Board Counsel, noted 15 agenda item 13 was an Order to Show Cause and an Answer that had been filed in the case of Nikolas 16 17 Kernich. She stated the Board reviewed the matter 18 and would schedule that case for a hearing before the 19 Board at a future meeting.] 20 + + +21 Report of Board Chairperson 22 [Christine Roussel, Pharm.D., BCOP, BCSCP, 23 Chairperson, stated the Board discussed the 24 consideration of submitting draft language around 25 regulations for the revision of the second part of

1 their regulations.]

2 \* \* \* 3 Report of Acting Commissioner 4 [Arion R. Claggett, Acting Commissioner, Bureau of 5 Professional and Occupational Affairs, addressed 6 Pennsylvania's Cancer Drug Repository Program. He 7 wanted to promote the program, because it promotes 8 access to lifesaving cancer drugs and treatment for 9 Pennsylvanians, regardless of their ability to pay by 10 permitting participating pharmacies to accept donated 11 unused cancer drugs and dispense them to qualifying individuals. 12 13 Acting Commissioner Claggett reported only 2 out 14 of 3,500 pharmacies in Pennsylvania are participating

14 of 3,500 pharmacles in Pennsylvania are participating 15 in the program. He noted recently sending an email 16 blast trying to promote it again and reported 17 receiving 7 applications.

18 Chair Roussel encouraged Ms. Elliott and Mr. 19 Jones to send the email blast to their members also. 20 Acting Commissioner Claggett addressed having 21 Board meetings at pharmacy schools. He noted the 22 schools include Wilkes-Barre, Lake Erie College of 23 Osteopathic Medicine (LECOM), Jefferson, St. Joseph's 24 University, University of Pittsburgh, and Duquesne 25 University. He asked when the Board wished to set up

1 that meeting.

2 Mr. Esterbrook suggested selecting a school that 3 has availability when school is in session to reach 4 more students.

5 Ms. Talbott mentioned that LECOM students may go 6 year-round and suggested going to Philadelphia in 7 October and considering Pittsburgh next year.

8 Chair Roussel commented that visiting one school 9 a year might be a reasonable attempt for the Board 10 and investigate for availability for October.

Acting Commissioner Claggett offered to reach out to St. Joseph's first for October of 2024, and would provide an update at the next meeting.

14 Chair Roussel mentioned that Jefferson might be a 15 good second if not St. Joseph's in October of 2024. 16 She noted they may decide to go to Pittsburgh for 17 October and then maybe next year look at the April 18 time frame. She mentioned the Board can communicate 19 with the Pittsburgh schools for maybe April of 2025.] \* \* \* 20 21 Report of Board Administrator - No Report 22 \* \* \* 23 Report of Board Members 24 [Janet Getzey Hart, R.Ph., addressed her attendance, 25 along with Ms. Talbott, at NABP Headquarters for a

1 Committee on Law Enforcement/Legislation

2 presentation. She explained that the committee 3 brings together NABP members from various states to 4 discuss certain topics or charges that NABP would 5 like to consider. She mentioned there were three 6 charges of this particular committee.

7 Ms. Getzey Hart noted the first one was the 8 development of model laws and regulations based on 9 resolutions adopted by the members of the association 10 or reports of task forces or other committees of the 11 association assigned by the executive committee.

12 Ms. Getzey Hart noted the second one was review 13 and comment on existing legislation and rules 14 governing the practice of pharmacy and the 15 distribution of prescription medications. She noted 16 the third one was to recommend to the executive 17 committee model pharmacy practice or prescription 18 drug distribution regulations, which are needed to be 19 improved for the protection of the public.

20 Ms. Getzey Hart noted discussion involving 21 recommendations of some of the task forces that had 22 been convened by NABP.

Ms. Talbott stated the reconfiguring of the model act and regs around automation and technology was timely. She mentioned that their recommendations for

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the task force have to go to the Executive Committee 1 2 (EC) and then will be added to the model act and the 3 model reqs. She mentioned that NABP moves a little 4 faster than the regulatory process in Pennsylvania 5 and should be done by June of 2024. Ms. Talbott noted there were other topics 6 7 reviewed from different states, but one is timely. 8 They will have to watch for the report to come after 9 the EC's review.] 10 \* \* \* 11 Appointment - NABP Exam Eligibility Services 12 Presentation 13 [Neal Watson, Member Relations and Government Affairs 14 Director, National Association of Boards of Pharmacy, 15 stated NABP has been around since 1904 with the mission of protecting public health, as well as 16 aligning with member boards of pharmacy to provide 17 18 services and programs to assist all of the boards of 19 pharmacy. 20 Mr. Watson noted that all of the boards of 21 pharmacy are members, and the biggest part of 22 participation is with the Electronic Licensure 23 Transfer Program (eLTP) to ensure the information is 24 shared from one board of pharmacy to another. 25 Mr. Watson referred to all of the programs and

1 services available to the boards of pharmacy, 2 including their competency assessment between the 3 North American Pharmacist Licensure Examination 4 (NAPLEX), Multistate Pharmacy Jurisprudence 5 Examination (MPJE) or Foreign Pharmacy Equivalency 6 Examination Committee, eLTP, disciplinary 7 clearinghouse, and continuing pharmacy education 8 (CPE) monitor program.

9 Mr. Watson addressed their pharmacy wholesaler 10 and supply chain, inspection, and compliance 11 programs. He noted their Verified Pharmacy Program 12 (VPP) and supply chain inspections are available for 13 sterile compounding, nonsterile, and general and resident pharmacies, along with their supply chain 14 15 inspection program and wholesale distributor 16 inspections.

Mr. Watson mentioned all of that is closely tied to their accreditation with six different pharmacy accreditations and distribution accreditation, formerly known as Verified-Accredited Wholesale Distributor (VAWD), now known as Drug Distributor Accreditation.

23 Mr. Watson announced their upcoming annual 24 meeting in May of 2024, as well as their program 25 review and training in July of 2024 that is available

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for board members and staff to understand everything 1 2 they do to correspond and work together as a team. 3 Mr. Watson addressed the exam eligibility process 4 and referred to their competency assessment services. 5 He noted it to be a new service within the last five 6 years. He mentioned trying to have a paperless, 7 seamless experience for exam candidates for new 8 graduates, as well as individuals that are trying to 9 transfer their license and taking the MPJE. 10 Mr. Watson stated their transcript services is a 11 great tool for the boards of pharmacy to take 12 advantage of. Transcripts are received directly from 13 the school of pharmacy, which is placed in the e-14 Profile for each individual going through the exam 15 process. He noted there is a secure portal that all 16 boards of pharmacy staff may access for reviewing 17 exam scores, the disciplinary clearinghouse, and 18 inspections performed through VPP or supply chain 19 inspections.

20 Mr. Watson addressed the eligibility process for 21 Pennsylvania and explained that new graduates would 22 go to NABP's website and apply for the NAPLEX and/or 23 MPJE. He further explained that a request is sent 24 and queued up through the NABP e-Profile connect 25 system that triggers a board of pharmacy staff member

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1 to log in and grant them eligible to take the exam, 2 which then triggers an authorization to test to go to 3 that candidate.

4 Mr. Watson addressed the new process, where the 5 candidate applies to take the NAPLEX and/or MPJE and 6 then NABP does that verification of the transcripts 7 and reviews anything in their clearinghouse and then 8 confirm or deny. He stated once NABP deems them 9 eligible to take the NAPLEX and MPJE then the 10 candidate receives their eligibility and can schedule 11 their exam and get authorization to test.

Mr. Watson informed Board members that the State 12 13 Board of Pharmacy will make all final decisions 14 regarding the issuance of licenses. He mentioned 15 that NAPLEX and MPJE is owned and operated by NABP, as well as administered. NABP will assist and deem 16 17 individuals eligible, which then allows the boards of 18 pharmacy to continue their efforts in making 19 licensure decisions once those exams are passed and 20 the information is received.

21 Mr. Watson noted the candidate would schedule and 22 take both exams. The exam results are then sent to 23 the same NABP e-Profile connect portal, where the 24 State Board of Pharmacy staff can interact, collect 25 the score, and deem the candidate eligible. He

1 emphasized that the transcripts from the schools of 2 pharmacy are also available at that point in the same 3 portal and again allows the Board an opportunity to 4 download and retain that information.

5 Ms. Talbott commented that it could speed up the 6 process of getting an Authorization to Test (ATT), 7 but the Board staff would still have to validate some 8 information like a background check. She mentioned 9 the test could be taken earlier, but there could be a 10 backup on the other side.

Mr. Watson stated NABP hoped there would be one 11 12 less process to worry about on the Board's end, and 13 then could hopefully free up a little more time to 14 worry about the licensure decision and other 15 requirements, like the background check. He reported that the 14 boards of pharmacy that utilize this now 16 17 line up all of those licensure requirements, get the 18 application background, and then match that to the 19 passing exam score when they are alerted and it is 20 uploaded into the portal as well as receiving the 21 transcript.

22 Chair Roussel asked whether the Pennsylvania 23 Licensing System (PALS) already interfaces with NABP 24 to get test scores, because it sounds like 25 transcripts may have to be downloaded and moved into

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1 PALS.

2	Ms. Townley explained that the file is currently
3	pulled from NABP's site, and the scores imported into
4	PALS directly. She noted it is only a one or two
5	step process to import the scores, and the transcript
6	would have to be manually added to the system. She
7	stated they currently do not accept transcripts, but
8	complete the education verification form that also
9	verifies the intern hours. She noted they require
10	the education and intern hours be reviewed before
11	eligibility.
12	Ms. Talbott commented that since they are
13	accepting all of the intern hours through the school
14	that it is kind of a moot point.
15	Mr. Watson stated the information would be on the
16	transcript and staff would have access. That is
17	where it gets intertwined between a licensure
18	decision or a licensure process and what is required
19	there versus what is required to take the exam. He
20	noted the goal is to consider the administrative
21	burden in attempting a seamless experience.
22	Mr. Watson referred to the graduation peak
23	season, noting it eliminates much of the back and
24	forth between NABP and the jurisdiction and confusion
25	with a new graduate in scheduling an exam. He

1 addressed the data stream of communication between 2 their system and the boards of pharmacy to share test 3 scores and input of available data.

Mr. Watson noted there is an \$85 one-time fee per 4 5 jurisdiction for both examinations, which includes failed attempts for that one-year period. He stated 6 7 NABP does follow the rules for license transfer 8 purposes provided by each board of pharmacy. Не 9 again mentioned the tie with the disciplinary 10 clearinghouse that all boards of pharmacy report to 11 NABP and have that information upfront to verify 12 state license or registration and identify any prior 13 discipline, including new graduates.

14 Mr. Watson stated NABP does contact the boards of 15 pharmacy with any major discipline during the 16 process, so they could make that decision jointly. Mr. Watson addressed the implementation process, 17 18 noting NABP requests about 40 to 60 days to 19 implement. He mentioned that it is easier to 20 implement prior to graduation season. He noted NABP 21 wants to assure that any rules applied for 22 Pennsylvania work, and the new technology rules have 23 the quality insurance check. He mentioned NAPB will 24 also send out communication in a joint effort with 25 the Board of Pharmacy to make sure all of the schools

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1 are aware of the change and provide steps or 2 instructions to assist new graduates on the new 3 process.

4 Chair Roussel wanted to make it clear that it 5 would not be for the current graduation period for 6 any students listening, and proper notice would be 7 given. She also noted the importance of considering 8 an additional \$85 fee to licensees or those applying 9 by using this service.

10 Ms. Talbott requested information regarding the 11 current turnaround time from the time a candidate 12 applies until obtaining their ATT for states that use 13 the program.

Mr. Watson explained that it averages around 15 days to process the application, noting it is decreasing rapidly with the implementation of electronic technology.

18 Chair Roussel commented that everybody graduates 19 at once, and there is a lot of pressure to get those 20 ATTs, but once students get the ATT, most schedule 21 tests 30-45 days out, which gives the Board more time 22 to process.

23 Mr. Claggett thanked Mr. Watson for his 24 presentation. He stated the Board will evaluate what 25 he presented in comparison to their internal process.

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He noted the current processing time for all 1 2 applications is around seven days but will reevaluate 3 everything and get back with him. Mr. Watson, on behalf of NABP, thanked everyone 4 5 for their service in protecting the public health.] \* \* \* 6 7 Discussion Items - Establishing PERC Guidelines 8 [Ariel E. O'Malley, Esquire, Board Counsel, stated 9 the Board has had several cases on their agenda over 10 the past year for disciplinary matters, specifically 11 compounding cases where they review the discipline 12 and violations but wondered whether the individuals 13 learned to correct the problem. 14 Ms. O'Malley mentioned that after several 15 discussions with Ms. Townley and Board members that she informed them that the State Board of Nursing has 16 Practice, Education, Remediation, and Collaboration 17 18 (PERC) agreements and do remedial education with 19 nurses to help them remediate whatever went wrong. 20 She noted there are confidential consent agreements, 21 where prosecution enters into them with the 22 respondent and come up with educational courses to 23 help them remediate and learn from the mistakes. She 24 explained that it is not necessarily punitive but 25 more in line with helping to remediate what happened

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1 and teaching them the correct way to do it, so it 2 does not happen again.

3 Ms. O'Malley noted discussion with Board members 4 to set that up for pharmacy cases, specifically 5 giving it a test run with compounding pharmacies. Carole Clarke Smith, Esquire, Senior Board 6 7 Counsel, informed Board members that PERC originally stood for Practice, Education, and Remediation 8 9 Committee, and the Nursing Board set up their 10 committee around 2011 to review complaints. She mentioned the Board felt like they were getting some 11 12 mandated reports from some facilities, where it might 13 be mandated to report things.

14 Ms. Clarke Smith explained that the Nursing Board 15 was concerned that a certain segment of their 16 licensees were getting disciplined for things that 17 they knew were happening all around, but they were 18 not getting the reports. She mentioned it also came 19 about because of the just culture movement, where one 20 of their board members was very involved in getting 21 just culture implemented in her facility and was one 22 of the driving forces.

23 Ms. Clarke Smith noted that PERC now stands for 24 Practice, Education, Remediation, and Collaboration. 25 She mentioned that one of the things that is part of

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1 the eligibility requirements for the nurse program is 2 employers willing to work with their nursing practice 3 advisors who work with prosecutors to help set up the 4 remedial education.

5 Ms. Clarke Smith stated the Board could decide who they want to designate as the point person, 6 7 noting they would have to recuse like the member of the Probable Cause Screening Committee. 8 She 9 mentioned that the Board of Nursing came up with 10 eligibility criteria from the just culture criteria 11 and looking at certain types of complaints that would 12 lend themselves to this type of agreement.

Ms. Clarke Smith also noted they came up with exclusionary criteria and never do a PERC agreement for certain things, including drug or substance abuse, patient abuse, fraud or deceit in the practice of nursing, pending criminal charges, drug diversion, reckless conduct, deceitful behavior, sexual misconduct, and intentional misconduct.

20 Ms. Clarke Smith explained that one of the main 21 tenets of putting someone in the PERC program is 22 either just a knowledge deficit or system error. She 23 believed starting with compounding pharmacies is a 24 great idea, and the Board will need to come up with 25 types of cases or complaints so that prosecution has

a guide for things being funneled into the PERC
program, along with a list of exclusionary items.
Ms. Clarke Smith offered to help guide the Board
through the process and offered to share a document
that the Board of Nursing developed to help set it
up.

7 Ray J. Michalowski, Esquire, Senior Board 8 Prosecutor, also informed Board members that a 9 similar program was set up for the Appraiser Board 10 called a remedial diversion program and is a little different than PERC. He noted that he would like to 11 12 do the same thing for the Board, where they copied 13 off of other states that had conditional dismissals 14 and would go to national meetings.

15 Mr. Michalowski stated it was difficult to set up 16 in Pennsylvania because of the separation of the 17 Board and prosecution but managed to do it to the 18 point that they were able to get their highest rating 19 in the federal audit of the Appraiser Board this 20 year. He mentioned that it is basically a 21 competency-based issue that is a first-time offense 22 or first time within a certain number of years 23 utilizing national guidelines to grade things. 24 Mr. Michalowski Reported that the program has 25 been extremely successful and are able to run it

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through just prosecution without having to include 1 2 the board. He noted it is monitored by the board's 3 Probable Cause Screening Committee to review remedial diversion agreements and offered to share those with 4 5 the Board. He mentioned receiving some monetary 6 compensation just to help the board pay for the 7 program but that it is much less than a typical fine 8 and is sort of a cost of the program, not even a cost 9 of investigation.

10 Mr. Michalowski explained that they use off-the-11 shelf courses that are either for qualifying or 12 continuing education. He mentioned that compounding 13 pharmacies would be a great place to start but 14 addressed two issues. He noted the first issue is 15 when there is a compounding pharmacy issue that they 16 can send the pharmacist in charge to classes and then 17 have the pharmacy that they may need to deal with. 18 Mr. Michalowski noted the second one is the 19 availability of compounding courses in a timely 20 manner. He endorsed the program but believed there 21 will be a lot of work to get it up and going. Нe

22 addressed their thoughts with some of the compounding 23 pharmacies themselves, not the pharmacists in charge, 24 which would be remedial programming but the

25 pharmacies that do not have the ability to handle

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1 compounding properly because their pharmacist in 2 charge may leave tomorrow and the same ownership is 3 still in place.

Mr. Michalowski mentioned that some of the places 4 5 that are not getting it may be made part of a future 6 probation condition by requiring them to get 7 accredited by NABP's compounding accreditation 8 program. He noted that would be on the opposite side 9 of PERC, where PERC is trying to be non-disciplinary, 10 and would be more for the problem child pharmacies that have visited them more than a few times and need 11 12 to meet that higher standard.

13 Chair Roussel commented that the Board would love 14 to see documentation from both boards as they look 15 toward finding a better way to improve competency.

Ms. Talbot asked whether Mr. Michalowski or Ms. 16 17 Clarke Smith will be there to guide the Board. She 18 also asked Mr. Watson to see if any other states do 19 this across the country, and Mr. Watson agreed. She 20 recommending having a task force to review the 21 information and having a meeting between the meetings 22 of the task force to bring the information back to 23 the general Board.

Ms. O'Malley offered to work on the informationMr. Watson supplies internally, along with Ms. Clarke

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Smith, Mr. Michalowski, and Mr. Giunta and then bring 1 2 the information back to the Board. 3 Chair Roussel mentioned that the exclusion 4 criteria from the State Board of Nursing was very 5 consistent with what the exclusion criteria would be 6 for the State Board of Pharmacy.] 7 \* \* \* 8 Discussion Items - Availability of Pharmacy Schools 9 [Christine Roussel, Pharm.D., BCOP, BCSCP, 10 Chairperson, noted the availability of pharmacy 11 schools was addressed under the Report of Acting Commissioner.] 12 13 \* \* \* 14 FYI Items - Current Income Levels for Participation 15 in the Cancer Drug Repository Program [Christine Roussel, Pharm.D., BCOP, BCSCP, 16 17 Chairperson, referred for FYI items, and stated the 18 current income levels for participation for the 19 Cancer Drug Repository Program has been posted to the 20 Board of Pharmacy website in support of Acting 21 Commissioner Claggett and the Board of Pharmacy's 22 desire to help increase enrollment and utilization of 23 the Cancer Drug Repository Program.] \* \* \* 24 25 FYI Items - Coalition for Responsible Compounding

1 Letter to the Board 2 [Christine Roussel, Pharm.D., BCOP, BCSCP, 3 Chairperson, noted the Board wanted to acknowledge the receipt and reading of the Coalition for 4 5 Responsible Compounding letter to the Board.] \* \* \* 6 7 FYI Items - NABP - Redesigned Medication Safety Website for Consumers 8 9 [Christine Roussel, Pharm.D., BCOP, BCSCP, 10 Chairperson, stated NABP has many resources, one of 11 which is their medication safety website for 12 consumers. She informed everyone that it has 13 recently been redesigned and recommended pharmacists 14 take a moment to review that. She also wanted to 15 place it on the Board of Pharmacy's website, noting 16 it is helpful for laypersons and a good resource for consumers wanting to buy medications online. 17 18 Larry Jones, Executive Director, Pennsylvania 19 Society of Health-System Pharmacists, also requested 20 the information for a posting in their newsletter, 21 and Chair Roussel offered to send the link.] \* \* \* 22 23 Old Business - Newsletter Articles 24 [Christine Roussel, Pharm.D., BCOP, BCSCP, 25 Chairperson, asked whether anybody had any

recommendations for newsletter articles and received 1 2 no reply.] 3 \* \* \* 4 MOTIONS: 5 CHAIRPERSON ROUSSEL: 6 Are there any motions to approve agenda 7 item 3, Case No. 22-54-012817? 8 MR. ESTERBROOK: 9 So moved. 10 ACTING COMMISSIONER CLAGGETT: 11 Second. 12 CHAIRPERSON ROUSSEL: 13 Any discussion? We'll call the vote. 14 15 Esterbrook, aye; Roussel, aye; Claggett, 16 aye; Ritchie, aye; Talbott, aye; Hart, aye; Slagle, aye. 17 18 [The motion carried unanimously. The Respondent's 19 name is Anthony Afamefuna Okonkwo.] \* \* \* 20 21 CHAIRPERSON ROUSSEL: 22 For agenda item 4, Case No. 23-54-008408, 23 do we have any motions to accept? 24 MR. ESTERBROOK: 25 So moved.

31 ACTING COMMISSIONER CLAGGETT: 1 2 Second. 3 CHAIRPERSON ROUSSEL: 4 Any discussion? Let's call the vote. 5 6 Esterbrook, aye; Roussel, aye; Claggett, 7 aye; Ritchie, aye; Talbott, recuse; Hart, 8 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 Pennsylvania CVS Pharmacy, LLC, 12 d/b/a CVS Pharmacy 1321.] 13 \* \* \* 14 CHAIRPERSON ROUSSEL: 15 Moving to agenda item 6, Case No. 20-54-16 000737, do we have any motions to accept? 17 MR. ESTERBROOK: 18 So moved. ACTING COMMISSIONER CLAGGETT: 19 20 Second. 21 CHAIRPERSON ROUSSEL: 22 Any discussion? I will call the vote. 23 Esterbrook, aye; Roussel, aye; Claggett, 24 25 aye; Ritchie, aye; Talbott, aye; Hart,

32 1 aye; Slagle, aye. 2 [The motion carried unanimously. The Respondent's 3 name is Empower Pharmacy.] \* \* \* 4 5 CHAIRPERSON ROUSSEL: 6 Moving on to agenda item 7, Case No. 21-7 54-012717, do we have a motion to accept? 8 MR. ESTERBROOK: 9 So moved. 10 ACTING COMMISSIONER CLAGGETT: 11 Second. 12 CHAIRPERSON ROUSSEL: 13 Any discussion? I will call the vote. 14 15 Esterbrook, aye; Roussel, aye; Claggett, 16 aye; Ritchie, aye; Talbott, aye; Hart, 17 aye; Slagle, aye. 18 [The motion carried unanimously. The Respondent's 19 name is MEI Services, Inc.] \* \* \* 20 21 CHAIRPERSON ROUSSEL: 22 For agenda item 8, Case No. 22-54-001657, 23 do I have a motion to accept? 24 MR. ESTERBROOK: 25 So moved.

ACTING COMMISSIONER CLAGGETT: 1 2 Second. 3 CHAIRPERSON ROUSSEL: 4 Any discussion? Let's call the vote. 5 6 Esterbrook, aye; Roussel, aye; Claggett, 7 aye; Ritchie, aye; Talbott, aye; Hart, 8 aye; Slagle, aye. 9 [The motion carried unanimously. The Respondent's 10 name is Phillip David Sebrell, R.Ph.] \* \* \* 11 CHAIRPERSON ROUSSEL: 12 13 For agenda item 9, Case No. 23-54-017189, 14 do I have a motion to accept? 15 MR. ESTERBROOK: 16 So moved. 17 ACTING COMMISSIONER CLAGGETT: 18 Second. 19 CHAIRPERSON ROUSSEL: 20 Any discussion? Let's call the vote. 21 22 Esterbrook, aye; Roussel, aye; Claggett, 23 aye; Ritchie, aye; Talbott, aye; Hart, 24 aye; Slagle, aye. 25 [The motion carried unanimously. The Respondent's

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34 1 name is Revive Rx.] \* \* \* 2 3 CHAIRPERSON ROUSSEL: 4 Agenda item 14, Paul Carmen Scota t/d/b/a 5 Lehigh Pharmacy & Paul Carmen t/d/b/a 6 Wynnefield Pharmacy, Case Nos. 23-54-7 010128 & 23-54-017999. 8 Do we have any motions? 9 MS. O'MALLEY: I believe the Board would entertain a 10 motion to grant the Commonwealth's motion 11 for default and to have counsel draft an 12 13 Adjudication in accordance with 14 discussions in Executive Session. 15 MR. ESTERBROOK: 16 So moved. ACTING COMMISSIONER CLAGGETT: 17 18 Second. 19 CHAIRPERSON ROUSSEL: 20 Any discussion? We shall call the vote. 21 22 Esterbrook, aye; Roussel, aye; Claggett, 23 aye; Ritchie, aye; Talbott, aye; Hart, 24 aye; Slagle, aye. 25 [The motion carried unanimously.]

35 \* \* \* 1 2 CHAIRPERSON ROUSSEL: 3 Item 15, the Adjudication and Order for 4 Mandy Fadakar, Case No. 22-54-005461. Do 5 we have a motion to accept? MR. ESTERBROOK: 6 7 So moved. 8 ACTING COMMISSIONER CLAGGETT: 9 Second. 10 CHAIRPERSON ROUSSEL: 11 Any discussion? Let's call the vote. 12 13 Esterbrook, aye; Roussel, aye; Claggett, 14 aye; Ritchie, aye; Talbott, aye; Hart, 15 aye; Slagle, aye. 16 [The motion carried unanimously.] \* \* \* 17 18 Review of Applications 19 CHAIRPERSON ROUSSEL: 20 Item 16, the Review of the Application of Sahr Samuel Gbakima for Review of the 21 22 Pharmacist License Application. 23 The motion would be to accept his 24 Application to retest. 25 MR. ESTERBROOK:

36 So moved. 1 2 ACTING COMMISSIONER CLAGGETT: 3 Second. 4 CHAIRPERSON ROUSSEL: 5 Any discussion? Let's call the vote. 6 7 Esterbrook, aye; Roussel, aye; Claggett, 8 aye; Ritchie, aye; Talbott, aye; Hart, 9 aye; Slagle, aye. 10 [The motion carried unanimously.] \* \* \* 11 12 Board Counsel - Legislative Report (cont.) 13 [Ariel E. O'Malley, Esquire, Board Counsel, noted Ms. 14 Talbott to be correct earlier when she said it covers 15 all of the childhood vaccines.] \* \* \* 16 Report of Board Prosecution 17 18 [Ray J. Michalowski, Esquire, Senior Board 19 Prosecutor, informed Board members that Tyesha Miley 20 joined the prosecution team. He also noted Glenn 21 Masser accepted a position with the Department of 22 Environmental Protection but will be at the next 23 Board meeting. 24 Chair Roussel welcomed Ms. Miley to the State 25 Board of Pharmacy and also noted the Board enjoyed

1 working with Mr. Masser.] \* \* \* 2 3 Public Comment 4 [Larry Jones, Executive Director, Pennsylvania 5 Society of Health-System Pharmacists, noted having a 6 hospital-owned retail pharmacy inspector inspect two 7 recent pharmacies in the same health system who wrote 8 up the pharmacy for not having a squirt record. Нe 9 believed it to be a cleaning record of the external 10 topical products area. 11 Mr. Jones mentioned the inspector noted it to be 12 terminology he used in all of his retail pharmacy 13 inspections. He stated the inspector could not quote 14 a regulation, but they satisfied some of his requests 15 with the cleaning documentation record. He stated a

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16 squirt record is a term that has been used with 17 controlled substances and diversion in the past. He 18 reported the inspector to be a pharmacy inspector in 19 the City of Philadelphia.

20 Mr. Michalowski stated a routine inspection falls 21 on the Board side before it gets to them with a 22 failed inspection on the prosecution side. He noted 23 that since the pharmacy compounding rules have gone 24 into effect that he did not know whether the Board 25 has gotten together with the Bureau of Enforcement

and Investigation's (BEI) individuals in charge of the inspectors to possibly update the inspection checklist. He suggested examining whether the checklists had been updated generally with BEI and to ask for a copy of the portion that is actually graded and the questions that support it.

7 Chair Roussel asked whether the inspection 8 checklist is universal for all pharmacies as opposed 9 to ones that perform nonsterile compounding and 10 sterile compounding.

Mr. Michalowski stated Pennsylvania only has one 11 12 type of pharmacy, because they do not license 13 separately. He reported having only one checklist 14 with questions that would apply. He mentioned that 15 before the compounding regs were in place that they were inspecting compounding pharmacies using the 16 17 overall term that says they must have the proper 18 equipment, facilities, and resources necessary to do 19 the type of pharmacy work being performed.

20 Mr. Michalowski stated they now have specific 21 regs to refer to but was not sure it has changed 22 since the time they basically went off of that one 23 question in the background, whether they had the 24 right setup to do the type of pharmacy they were 25 performing.

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1 Victoria Elliott, RPh, MBA, CAE, CEO, 2 Pennsylvania Pharmacists Association, noted their 3 organization submitted a request for the presence of 4 a State Board of Pharmacy member at their upcoming 5 legislative day on April 8, 2024, to interact with 6 some of their students. She mentioned the request 7 did not make it on the agenda but made the request in 8 She noted the visits will take place in person. 9 their office right across from the Capitol. 10 Acting Commissioner Claggett informed Ms. Elliott 11 that they could have a discussion after the meeting.] 12 13 Upcoming Meeting Dates 14 [Christine Roussel, Pharm.D., BCOP, BCSCP, 15 Chairperson, reminded everyone that the next 16 scheduled Board meeting is April 30, 2024, in 17 Harrisburg. 18 Chair Roussel informed students attending the 19 meeting that the presentation from NABP about 20 licensure was informational and does not change 21 anything the Board is doing at this time.] 22 23 Adjournment 24 CHAIRPERSON ROUSSEL: 25 I would entertain a motion to adjourn.

MR. ESTERBROOK: Motion to close. MR. ESTERBROOK: Motion to close. ACTING COMMISSIONER CLAGGETT: Second. CHAIR ROUSSEL: Any discussion? Any opposed? Motion granted. Meeting adjourned. \* \* \* [There being no further business, the State Board of Pharmacy Meeting adjourned at 11:50 a.m.] \* \* \* 

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2	CERTIFICATE
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4	I hereby certify that the foregoing summary
5	minutes of the State Board of Pharmacy meeting, was
6	reduced to writing by me or under my supervision, and
7	that the minutes accurately summarize the substance
8	of the State Board of Pharmacy meeting.
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11	Manden dela
12	Madeline Helmstetter,
13	Minute Clerk
14	Sargent's Court Reporting
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1 2 2		STATE BOARD OF PHARMACY REFERENCE INDEX	
1 2 3 4 5		March 19, 2024	
6 7 8	TIME	AGENDA	
9 10	9:00 10:30	Executive Session Return to Open Session	
11 12 13	10:30	Official Call to Order	
14 15	10:31	Introduction of Board Members/Audience	
16 17	10:33	Approval of Agenda	
18 19	10:33	Approval of Minutes	
20 21	10:35	Report of Board Prosecution	
22 23	10:43	Report of Board Counsel	
24 25	10:48	Report of Board Chairperson	
26 27	10:49	Report of Acting Commissioner	
28 29	10:54	Report of Board Members	
30 31 32 33 34	10:56	Appointment - Neal Watson, Member Relations and Government Affairs Director, NABP Exam Eligibility Services Presentation	
35 36	11:19	Discussion Items	
37 38	11 <b>:</b> 35	FYI Items	
39 40	11 <b>:</b> 35	Old Business	
41 42	11 <b>:</b> 36	Motions	
43 44	11:42	Review of Applications	
45 46	11:43	Report of Board Counsel (cont.)	
40 47 48	11:43	Report of Board Prosecution (cont.)	
49 50	11:45	Public Comment	
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			43
1 2 3 4 5 6 7 8 9		STATE BOARD OF PHARMACY REFERENCE INDEX (cont.) March 19, 2024	
5		March 19, 2024	
6 7 0	TIME	AGENDA	
9 10	11:50	Upcoming Meeting Dates	
11 12	11:50	Adjournment	
13 14			
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