1	COMMONWEALTH OF PENNSYLVANIA
2	DEPARTMENT OF STATE
3	BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
4	
5	FINAL MINUTES
6	
7	MEETING OF:
8	
9	STATE BOARD OF PHARMACY
10	
11	TIME: 9:00 A.M.
12	
13	PENNSYLVANIA DEPARTMENT OF STATE
14	Board Room C
15	One Penn Center
16	2601 North Third Street
17	Harrisburg, Pennsylvania 17110
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19	
20	August 28, 2018
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2 1 State Board of Pharmacy 2 3 August 28, 2018 4 5 BOARD MEMBERS: 6 7 Janet Getzey Hart, R.Ph., Chairperson 8 Katelin Lambert, Deputy Commissioner, Bureau of Professional and Occupational Affairs, present on 9 10 behalf of Ian J. Harlow, Commissioner of 11 Professional and Occupational Affairs 12 Robert B. Frankil, R.Ph., Vice Chairman Theresa M. Talbott, R.Ph., Secretary 13 14 Gayle A. Cotchen, Pharm.D./MBA, R.Ph. 15 Patrick M. Greene, Esquire, Office of Attorney 16 General 17 Mark J. Zilner, R.Ph. - Absent 18 19 20 BUREAU PERSONNEL: 21 22 Kerry E. Maloney, Esquire, Board Counsel Ray Michalowski, Esquire, Board Prosecution Liaison 23 24 Keith E. Bashore, Esquire, Board Prosecutor 25 Julia Feld-Caralle, Esquire, Board Prosecutor 26 Heather J. McCarthy, Esquire, Board Senior Prosecutor Andrea L. Costello, Esquire, Board Prosecutor 27 28 Melanie Zimmerman, R.Ph., Executive Secretary 29 Devon Kenefick, Intern, Office of Chief Counsel, 30 Department of State 31 32 33 ALSO PRESENT: 34 Carl Harting, CVS Health 35 John Long, CVS Health 36 Jeffrey J. Mesaros, CVS Health 37 Kathie Simpson, RN, Executive Director, Secundum Artem 38 Reaching Pharmacists with Help and PA Nurse Peer 39 Assistance Program 40 Jim Reed, Walgreens 41 Andrew C. Harvan, Esquire, Pennsylvania Medical 42 Society 43 Jonathan Borowski, Penn State University Health 44 Services 45 Charles Hartwell, Esquire, Dethlefs-Pykosh Law Group 46 John Sisto, Express Scripts, Incorporated 47 Robert Grobinski, Cardinal Health 48 Greg Smith, Central Admixture Pharmacy 49 Judy Kutchman, AllianceRx Walgreens Prime 50 Jenna McCarthy

3 \* \* \* 1 2 State Board of Pharmacy 3 August 28, 2018 \* \* \* 4 5 The regularly scheduled meeting of the State Board of Pharmacy was held on Tuesday, August 28, 6 7 2018. Janet Getzey Hart, R.Ph., Chairperson, called 8 the meeting to order at 9 a.m. 9 The Pledge of Allegiance was recited. \* \* \* 10 11 Introduction of Board Members, Board Staff, and 12 Audience 13 [Chairperson Hart requested the introduction of Board 14 Members, Board staff, and audience members in 15 attendance. She also requested that all cell phones 16 and mobile devices be silenced. A quorum was noted to 17 be present.] \* \* \* 18 19 Evacuation Announcement 20 [Melanie Zimmerman, R.Ph., Executive Secretary, 21 reviewed the emergency evacuation procedures for One 22 Penn Center.] 23 \* \* \* 24 Approval of Agenda 25 CHAIRPERSON HART:

1 The first item is the approval of the 2 agenda. 3 MS. TALBOTT: 4 I'll make the motion that we approve the 5 agenda as written. 6 DR. COTCHEN: 7 I second that. 8 CHAIRPERSON HART: 9 Any discussion? All in favor? Opposed? 10 [The motion carried unanimously.] \* \* \* 11 12 Approval of Minutes of the June 28, 2018 meeting 13 CHAIRPERSON HART: 14 The next item on the agenda is the 15 approval of the minutes. I think 16 everyone was given those ahead of time. Were there any changes to the 17 18 minutes, or can we have a motion to 19 approve? 20 DR. COTCHEN: 21 I move that we approve the minutes as 22 presented. 23 MS. TALBOTT: 24 Second. 25 CHAIRPERSON HART:

5 Any discussion? Call for a vote. 1 All in 2 favor, aye? Opposed? 3 [The motion carried unanimously.] \* \* \* 4 5 Report of Prosecutorial Division 6 [Julia Feld-Caralle, Esquire, Board Prosecutor, 7 presented the Consent Agreements for File No. 13-54-8 05310 and File No. 17-54-07015.] \* \* \* 9 10 [Keith E. Bashore, Esquire, Board Prosecutor presented 11 the Consent Agreement for File No. 18-54-03896.] \* \* \* 12 13 [Ray Michalowski, Esquire, Board Prosecution Liaison, 14 announced a restructuring of the Legal Office and 15 introduced Heather McCarthy, Esquire, Senior 16 Prosecutor as the new Pharmacy Board Prosecution 17 Liaison. John Karl Geschwindt, Esquire, Board 18 Prosecutor, will be a new prosecutor for the Board.] \* \* \* 19 20 Report of Board Counsel 21 [Kerry E. Maloney, Esquire, Board Counsel, discussed 22 organizing a regulatory work session for the October 23 meeting. He noted a waiver request to waive the 24 requirement that pharmacies only use their registered 25 name. He suggested the use of a temporary waiver, as

a permanent waiver would require amending the
regulations.

There was discussion regarding the use a different name or adding doing business as (DBA) on the actual label, which would permit multiple names based upon a contractual agreement and be consistent with a regular pharmacy practice.

8 There also was a discussion related to offering 9 patients or members the ability to receive specific 10 materials related to specific health benefit plans. 11 There would be a contractual agreement for 12 accountability, which could be tracked the same as 13 Board discipline.

Mr. Michalowski addressed concerns with the disciplinary process as a result of the inability to appropriately trace the pharmacy or the bottle label having insufficient information. It was noted that there should be an accountability and traceability from the bottle back to the registered pharmacy.

Language changes and the ability of a registered pharmacy to register additional names for the Board to track was discussed.

23 Mr. Michalowski reviewed the inspection process 24 wherein the inspectors pull certain bottles to assure 25 that only approved labels are being used. Discussion

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continued related to the language in the current 1 2 regulations on the matter. 3 Mr. Maloney noted matters for discussion during 4 Executive Session. He stated Senate Bill 780 includes 5 telehealth, telemedicine, and telepharmacy provisions. Mr. Maloney stated the Board will review at its 6 7 next meeting the Compounding and General Revisions 8 regulations with Immunizations up next. He will 9 update the Board on any movement of its regulations. 10 He noted that a priority tag will be placed on 11 Compounding. Naloxone was submitted as final 12 omitted.1 \* \* \* 13 14 Report of Board Chairperson 15 [Chairperson Hart noted that the Board had conducted a review of Multistate Pharmacy Jurisprudence 16 17 Examination (MPJE) questions for inclusion on the 18 exam.] \* \* \* 19 20 Report of Probable Cause Screening Committee [It was noted that the Probable Cause Screening 21 2.2 Committee signed an immediate suspension order and a 23 medical examination order.] \* \* \* 24 25 Report of Deputy Commissioner

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1 [Katelin Lambert, Deputy Commissioner, on behalf of 2 Ian J. Harlow, Commissioner of Professional and 3 Occupational Affairs, provided an update on pharmacy 4 renewals. All pharmacists received an email 5 containing a registration code for the Pennsylvania 6 Licensing System (PALS).

Ms. Lambert stated legacy user IDs and passwords can be used. Renewal reminders will be sent to licensees during the renewal period. She also noted reminders for saved applications. Ms. Lambert referred to a self-service page for help and a support page for assistance with renewals that allows the submission of help desk tickets.

14 Ms. Zimmerman discussed referring all questions 15 regarding the Prescription Drug Monitoring Program (PDMP) to the PDMP. She reviewed the difference 16 17 between a renewal and an initial application. She 18 stated an initial application requires license 19 verifications for licenses that are held or were held, 20 but that a license verification is not required with 21 renewals.

Ms. Simpson stated the PA Nurse Peer Assistance Program has been inundated with questions, including being licensed in another state. She questioned whether a copy of an applicant's current license in

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another state should be provided. She also questioned 1 2 whether individuals under a Voluntary Recovery Program 3 agreement due to substance use are required to provide 4 details, like having contacted Secundum Artem Reaching 5 Pharmacists with Help Pharmacy Peer Assistance Program 6 (SARPH) and the Professional Health Monitoring 7 Programs (PHMP). Ms. Zimmerman noted the requirement to provide detailed information when a licensee must 8 9 answer "Yes" to a legal question. However, uploaded 10 unnecessary information will slow the processing of a 11 renewal.

12 Ms. Simpson wanted to clarify a confusion 13 regarding documentation needed for criminal charges issued by the Disciplinary Monitoring Unit (DMU) since 14 15 the last renewal and whether or not all documentation should be resent. Ms. Zimmerman stated the file 16 number would suffice. If there are criminal charges 17 18 or a conviction that has already been addressed by the 19 Board, the individual should include a statement that 20 the file number contains all of the necessary 21 information. 2.2 Ms. Simpson requested clarification regarding

22 Ms. Simpson requested clarification regarding 23 required documentation for driving under the influence 24 (DUI). Ms. Zimmerman stated documents do not need to 25 be certified but licensees should provide complete

1 information.

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2	Ms. Simpson suggested posting the guidelines for
3	renewal on the SARPH website.
4	It was noted that docket numbers will no longer
5	be used on new cases.
6	Mr. Michalowski discussed Act 6 regarding the
7	reporting of criminal matters, as well as registering
8	with PA's PDMP.
9	Mr. Michalowski addresses the receipt of medical
10	marijuana complaints which are related more to the
11	physician than to the dispensaries and completely
12	unrelated to pharmacies. Chairperson Hart noted
13	concerns with dealing with a pharmacist with a medical
14	marijuana card, which is a Schedule I controlled
15	substance under federal law. Mr. Michalowski
16	explained that Pennsylvania treats the individual the
17	same as somebody on an opioid pain killer or a
18	benzodiazepine for anxiety attacks. Hospitals have
19	trained individuals to determine impairment.
20	There was a discussion regarding the National
21	Association of Boards of Pharmacy (NABP) authorizing
22	students for licensure exams. Ms. Zimmerman added
23	that the Board did not enter into a contract with
24	NABP, and that the Board's office staff were able to
25	complete the task given the intern hours waiver. The

staff is working on test results posted on August 6,
2018.

3 Ms. Zimmerman stated the information technology 4 (IT) department is developing a program to automate 5 the issuance of licenses. She noted that older 6 applications converted to PALS need a final review 7 because of the old material. She also noted that intern hours were previously required before 8 9 authorization for the exams, and once the Board waived 10 that requirement for Pharm.D. graduates of ACPE-11 accredited schools of pharmacy, the applicants could 12 be authorized for the exams without a complete 13 application review (until a later date).

Ms. Zimmerman explained that processing times are still extended due to staff vacancies and untrained new employees. She stated that deadlines are being met where required with 30 days to evaluate a remodel application and 90 days for proposed pharmacy/change in location applications.

20 Mr. Maloney stated that the application process 21 was streamlined for pharmacy (business) applications 22 in PALS, which also gives the applicant more 23 responsibility to read the regulations and create a 24 checklist for compliance. He also stated the Board's 25 oversight will still be included through the

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1 inspection.

Ms. Lambert stated the Bureau of Enforcement and Investigation (BEI) is testing and finalizing their work and integrating the inspection information into PALS.

6 Chairperson Hart suggested seeing a change 7 regarding corporate level responsibilities for 8 pharmacists in charge of stores that cannot receive 9 emails from an outside source due to security 10 concerns.

11 There was a discussion related to the delays in 12 issuing pharmacy interns who have criminal charges an authorization to test. Ms. Zimmerman stated NABP does 13 14 not authorize individuals to take the exams. The 15 Board must provide the authorization. She noted that 16 students who are Pharm.D. graduates of an ACPE-17 accredited school no longer must earn intern hours outside of school and would be authorize based on 18 19 their educational documents alone.

20 Ms. Zimmerman next reviewed the authorization to 21 test process. Each individual must be registered on 22 NABP's website to take an exam in order for the Board 23 to authorize the individual to take the exam.] 24 \*\*\* 25 Report of Executive Secretary - No Report

\* \* \* 1 2 [The Board expressed its appreciation to Ms. Zimmerman 3 for the extra hours she put in regarding licensing 4 issues.] \* \* \* 5 6 Applications 7 [Melanie Zimmerman, R.Ph., Executive Secretary, referred to applications for discussion during 8 9 Executive Session.] 10 \* \* \* 11 New Business 12 [Melanie Zimmerman, R.Ph., Executive Secretary, stated 13 NABP requested the Board name a member to attend the 14 Interactive Member Forum, November 28-29, 2018.] 15 MS. TALBOTT: 16 I make a motion that we send Robert Brian 17 Frankil to the NABP Interactive Member 18 Forum. 19 DR. COTCHEN: 20 I second that motion. 21 CHAIRPERSON HART: 22 Any discussion? All in favor? Opposed? 23 [The motion carried unanimously.] \* \* \* 24 25 New Business (Continued)

	14				
1	[Melanie Zimmerman, R.Ph., Executive Secretary, noted				
2	a letter from Diane Wordinger regarding hesitancy when				
3	prescribing opioids				
4	The Board discussed pharmacy benefit manager				
5	issues, guidelines for prescribing and dispensing				
6	which are not laws/regulations and alternatives to				
7	treating pain other than with opioids, such as dry				
8	needling, acupuncture, and marijuana.]				
9	* * *				
10	[Pursuant to Section 708(a)(5) of the Sunshine Act, at				
11	10:18 a.m., the Board entered into Executive Session				
12	with Kerry E. Maloney, Esquire, Board Counsel, to				
13	receive legal advice and engage in quasi-judicial				
14	deliberations. The Board returned to open session at				
15	11:38 a.m.]				
16	* * *				
17	MOTIONS				
18	MR. MALONEY:				
19	The item on the agenda for the vote is				
20	the CVS Waiver Request. In accordance				
21	with discussions in Executive Session,				
22	I'm looking for a motion to grant in part				
23	and deny in part the waiver request.				
24	The granting of the waiver would be				
25	that the Pharmacy Board would waive the				

regulation to the extent that it would 1 2 remain consistent with the following: 3 Pharmacy may not display, advertise, or 4 use any name other than the name in which 5 it is registered unless the pharmacy has 6 a legal or contractual right to use an 7 affiliated name; however, the pharmacy 8 label shall contain the pharmacy's name 9 as registered with the Board or a 10 derivation of its name as approved by the Board and in accordance with the section 11 12 on the label requirements. To the extent that the waiver is any 13 14 broader than what was just read, that is 15 denied by the Board. After this motion, 16 if it passes, then I'll draft an actual 17 order to make that clear. 18 Does any voting Board member have any 19 question on the wording? 20 DR. COTCHEN: 21 So moved. 2.2 MR. FRANKIL: 23 Second. 24 CHAIRPERSON HART: 25 Call for a vote.

1 2 Frankil, aye; Greene, aye; Lambert, aye; 3 Hart, aye; Cotchen, aye; and Talbott, 4 recuse. 5 [The motion carried. Terry Talbott recused herself 6 from deliberations and voting on the motion.] \* \* \* 7 8 DR. COTCHEN: 9 I move that we approve the Consent 10 Agreements for the six VRP files, which 11 numbers are File No. 18-54-02974, File 12 No. 18-54-03740, File No. 18-54-004155, File No. 18-54-004644, File No. 18-54-13 14 004712, and File No. 18-54-005533. 15 MS. TALBOTT: 16 Second. 17 CHAIRPERSON HART: Any discussion? Call for a vote. 18 19 20 Frankil, aye; Greene, aye; Lambert, aye; 21 Hart, aye; Cotchen, aye; and Talbott, 22 aye. 23 [The motion carried unanimously.] \* \* \* 24 25 DR. COTCHEN:

I move that we approve the Consent 1 2 Agreement for File No. 17-54-07015. 3 MS. TALBOTT: Second. 4 5 CHAIRPERSON HART: Any discussion? Call for a vote. 6 7 Frankil, aye; Greene, aye; Lambert, aye; 8 9 Hart, aye; Cotchen, aye; and Talbott, 10 aye. 11 [The motion carried unanimously. The pharmacist's name is Jeffrey Tyson Lipman, R.Ph.] 12 \* \* \* 13 DR. COTCHEN: 14 15 I move that we approve the Consent Agreement for File No. 13-54-05310. 16 17 MS. TALBOTT: Second. 18 19 CHAIRPERSON HART: 20 Any discussion? Call for a vote. 21 22 Frankil, aye; Greene, aye; Lambert, aye; 23 Hart, aye; Cotchen, aye; and Talbott, 24 aye. 25 [The motion carried unanimously. The pharmacy's name

1 is Med-Fast Pharmacy Institutional.] \* \* \* 2 3 DR. COTCHEN: 4 I move that we approve the Consent 5 Agreement for File No. 18-54-03896. 6 MS. TALBOTT: 7 Second. 8 CHAIRPERSON HART: 9 Any discussion? Call for a vote. 10 11 Frankil, aye; Greene, aye; Lambert, aye; 12 Hart, aye; Cotchen, aye; and Talbott, 13 aye. 14 [The motion carried unanimously. The pharmacist's 15 name is Ryan A. Stout.] \* \* \* 16 17 DR. COTCHEN: 18 I move that we approve the final 19 Adjudication and Order for File No. 18-20 54-001801, Anthony J. Labashousky, R.Ph. 21 MS. TALBOTT: 22 Second. 23 CHAIRPERSON HART: 24 Any discussion? Call for a vote. 25

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Frankil, aye; Greene, aye; Lambert, aye; 1 2 Hart, aye; Cotchen, aye; and Talbott, 3 aye. 4 [The motion carried unanimously.] \* \* \* 5 6 DR. COTCHEN: 7 I move that we approve the final 8 Adjudication and Order for File No. 18-9 54-00106, Cape Drugs. 10 MS. TALBOTT: 11 Second. 12 CHAIRPERSON HART: 13 Any discussion? Call for a vote. 14 15 Frankil, aye; Greene, aye; Lambert, aye; 16 Hart, aye; Cotchen, aye; and Talbott, 17 aye. 18 [The motion carried unanimously.] \* \* \* 19 20 DR. COTCHEN: 21 I move that we grant the petition for 22 reinstatement submitted by Eric V. Fox, 23 R.Ph., File No. 18-54-03078. 24 MS. TALBOTT: 25 Second.

1 CHAIRPERSON HART: 2 Any discussion? Call for a vote. 3 4 Frankil, recuse; Greene, aye; Lambert, 5 aye; Hart, aye; Cotchen, aye; and 6 Talbott, aye. 7 [The motion carried. Robert Frankil recused himself 8 from deliberations and voting on the motion.] \* \* \* 9 10 DR. COTCHEN: 11 I move that we provisionally deny the 12 Application Appeal submitted by Min Qiang 13 Chen. 14 MS. TALBOTT: 15 Second. 16 CHAIRPERSON HART: Any discussion? Call for a vote. 17 18 19 Frankil, aye; Greene, aye; Lambert, aye; 20 Hart, aye; Cotchen, aye; and Talbott, 21 aye. 22 [The motion carried unanimously.] 23 \* \* \* 24 DR. COTCHEN: 25 I move that we deny the Request for

Reduced Intern Hours submitted by Hussein 1 2 Albu Mohammed and Viviane Farah. 3 MS. TALBOTT: Second. 4 5 CHAIRPERSON HART: 6 Any discussion? Call for a vote. 7 Frankil, aye; Greene, aye; Lambert, aye; 8 9 Hart, aye; Cotchen, aye; and Talbott, 10 aye. 11 [The motion carried unanimously.] \* \* \* 12 DR. COTCHEN: 13 14 I move that we provisionally deny the 15 Nonresident Pharmacy Application submitted by College Pharmacy. 16 17 MS. TALBOTT: Second. 18 19 CHAIRPERSON HART: 20 Any discussion? Call for a vote. 21 Frankil, aye; Greene, aye; Lambert, aye; 22 23 Hart, aye; Cotchen, aye; and Talbott, 24 aye. 25 [The motion carried unanimously.]

\* \* \* DR. COTCHEN: I move that we adjourn. MS. TALBOTT: Second. CHAIRPERSON HART: All in favor? [The motion carried unanimously.] \* \* \* [There being no further business, the State Board of Pharmacy Meeting adjourned at 11:46 a.m.] \* \* \* 

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2	CERTIFICATE
3	
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 of
8	the State Board of Pharmacy meeting.
9	
10	ALB-1
11	STOLOW State
12	Adam Beck,
13	Minute Clerk
14	Sargent's Court Reporting
15	Service, Inc.
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1 2 3		STATE BOARD OF PHARMACY REFERENCE INDEX	
5 4 5 6		August 28, 2018	
7	TIME	AGENDA	
8 9 10	9:00	Official Call to Order	
11	9:00	Pledge of Allegiance	
12 13 14 15	9:01	Introduction of Board Members, Board Staff, and Audience Members	
16 17	9:04	Approval of Agenda	
18 19	9:04	Approval of Minutes	
20	9 <b>:</b> 05	Report of Prosecutorial Division	
21 22	9:13	Report of Board Counsel	
23 24	9:28	Report of Committees	
25 26	9:29	Report of Deputy Commissioner	
27 28 29	10:14	New Business	
30 31 32	10:18 11:38	Executive Session Return to Open Session	
33 34	11:38	Motions	
35 36	11:46	Adjournment	
30 37 38			
39			
40 41			
42 43			
44 45			
46 47			
48 49			
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