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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

F I N A L M I N U T E S

MEETING OF:

STATE BOARD OF PHARMACY

TIME: 9:00 A.M.

PENNSYLVANIA DEPARTMENT OF STATE
Board Room C
One Penn Center
2601 North Third Street
Harrisburg, Pennsylvania 17110

March 5, 2019

State Board of Pharmacy

March 5, 2019

ALSO PRESENT: (Continued)

- Steve Sheaffer, Pennsylvania Society of Health-System Pharmacists
- Gregory Smith, Director of Pharmacy, Central Admixture Pharmacy Services
- David Klinger, Geisinger Health System
- Jeenu Philip, Walgreens
- James Reed, Area Healthcare Supervisor, Walgreens
- Kimberly Adams, Chief of Fiscal Management, Bureau of Finance and Operations
- Shannon Boop, Fiscal Management Specialist 1, Bureau of Finance and Operations
- Amanda Richards, Fiscal Management Specialist 2, Bureau of Finance and Operations
- Vince Lacroce, Pennsylvania Society of Health-System Pharmacists
- Sarah DiVello, Pharmacy Resident, Penn State Health Milton S. Hershey
- Linda Knor, Secundum Artem Reaching Pharmacists with Help and Pennsylvania Nurse Peer Assistance Program
- Kathie Simpson, RN, Executive Director, Secundum Artem Reaching Pharmacists with Help and Pennsylvania Nurse Peer Assistance Program

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1 ***

2 State Board of Pharmacy

3 March 5, 2019

4 ***

5 The regularly scheduled meeting of the State
6 Board of Pharmacy was held on Tuesday, March 5, 2019.
7 Terry Talbott, R.Ph., Chairperson, called the meeting
8 to order at 9:00 a.m.

9 The Pledge of Allegiance was recited.

10 ***

11 [Chairperson Talbott requested that all cell phones be
12 turned off.]

13 ***

14 Evacuation Announcement

15 [Melanie Zimmerman, R.Ph., Executive Secretary,
16 reviewed the emergency evacuation procedures for One
17 Penn Center.]

18 ***

19 Introduction of Board Members and Board Staff

20 [Chairperson Talbott requested the introduction of
21 Board members and Board staff.]

22 ***

23 [Chairperson Talbott welcomed Kalonji Johnson, Acting
24 Commissioner, who provided a brief summary of his
25 professional background.]

1 [Chairperson Talbott requested the introduction of
2 audience members in attendance.]

3 ***

4 Amendments to the Agenda

5 CHAIRPERSON TALBOTT:

6 Are there any additions to the agenda?

7 MR. MALONEY:

8 I would need a motion to add a discussion
9 of compounding regs.

10 CHAIRPERSON TALBOTT:

11 Discussion of compounding regs. We will
12 add that to the agenda.

13 Motion, please.

14 DR. COTCHEN:

15 So moved.

16 MR. FRANKIL:

17 Second.

18 CHAIRPERSON TALBOTT:

19 Any other discussion? All in favor? Any
20 opposed? I'll have a motion to accept
21 the agenda as amended.

22 DR. COTCHEN:

23 So moved.

24 MS. HART:

25 Second.

1 CHAIRPERSON TALBOTT:

2 Any discussion? All in favor?

3 [The motion carried unanimously.]

4 ***

5 Approval of Minutes of the January 8, 2019 meeting

6 CHAIRPERSON TALBOTT:

7 Are there any corrections, additions,
8 deletions to the January 8 meeting
9 minutes?

10 DR. COTCHEN:

11 Motion to approve minutes.

12 MS. HART:

13 Second.

14 CHAIRPERSON TALBOTT:

15 Any other discussion? All in favor? Any
16 opposed?

17 [The motion carried unanimously.]

18 ***

19 Report of Prosecutorial Division

20 [Heather J. McCarthy, Esquire, Board Prosecution
21 Liaison, apologized for not having the status report
22 concerning case numbers. She explained that the
23 Pennsylvania Licensing System (PALS) does not have
24 that capability yet and is scheduled for early summer
25 development.]

1 Ms. McCarthy addressed the Office of General
2 Counsel (OGC) Mediation Program. She noted that chief
3 counsel created an initiative to implement the program
4 last year, whereby Ms. Guilfoyle was tasked with
5 introducing the mediation program first to the Social
6 Work and Psychology Boards.

7 Ms. McCarthy stated two cases were successfully
8 mediated for those Boards. The program was being
9 opened up to all of the Boards. She described the
10 program as a free program and completely voluntary
11 with the goal of resolving cases quicker. She
12 explained the mediation process, noting it is still
13 completely up to the Board whether or not to accept
14 the consent agreement.

15 Ms. McCarthy commented that no cases were
16 identified that could not go through the mediation
17 process and explained mediation cases as case-
18 specific.]

19 ***
20 [Ms. McCarthy presented the Consent Agreement for File
21 No. 18-54-010544.]

22 ***
23 [Robert B. Frankil, R.Ph., Vice Chairman, exited the
24 meeting at 9:11 a.m. for recusal purposes]

25 ***

1 [J. Karl Geschwindt, Esquire, Board Prosecutor,
2 presented the Consent Agreement for File No. 18-54-
3 03100.]

4 ***

5 [Robert B. Frankil, R.Ph., Vice Chairman, reentered
6 the meeting at 9:14 a.m.]

7 ***

8 [Tara J. Smith, Esquire, Board Prosecutor, presented
9 the Consent Agreements for File No. 17-54-10065 and
10 File No. 18-54-010785.]

11 ***

12 Appointment - Bureau of Finance and Operations Annual
13 Budget Presentation

14 [Kimberly Adams, Chief of Fiscal Management, Bureau of
15 Finance and Operations, introduced herself and Amanda
16 Richards, Fiscal Management Specialist.

17 Ms. Adams addressed the licensee population from
18 a revenue standpoint which shows biennial growth.

19 Chairperson Talbott questioned whether
20 nonrenewals could be the reason the number of
21 pharmacists were down roughly 200 from last time.

22 Ms. Zimmerman explained that approximately 1,000
23 licensees were lost during the pharmacist renewals,
24 noting a overall decrease between the newly issued
25 licenses and those who chose not to renew.

1 Ms. Adams stated 97.4% of revenue was from
2 renewals and applications and a current biennial
3 total. She noted fee structure with the last fee
4 increase in 2005.

5 Ms. Adams reviewed the categorical breakdown of
6 administrative and legal expenses for FY 2016-17 and
7 FY 2017-18, FY 2018-2019 budget, and FY 2018-2019
8 expenses. She commented that expenses incur from
9 direct-based cost, timesheet-based charges, and
10 licensee-based charges.

11 Ms. Adams addressed the breakdown of current
12 Board member expenses for FY 2018-19, which is up.
13 She stated the budget for FY 2018-2019 was adequate.

14 Ms. Adams addressed revenues and expenses from FY
15 2016-2017, FY 2017-2018, and FY 2018-2019. She stated
16 the Board was in good shape financially due to the
17 increase in licensee population and revenue exceeding
18 expenditures.

19 Ms. Adams provided a breakdown of Board member
20 expenses for FY 2016-2017 and FY 2017-2018, noting a
21 budget for FY 2018-2019. She noted expenses as of
22 February 27. She stated the budget was also adequate
23 for FY 2019-2020. She commented that any excess goes
24 back to the restricted account for the Board's use.

25 Ms. Adams reviewed an expenditure sheet providing

1 a pictorial view of the fluctuation of expenses since
2 2006.]

3

4 Report of Board Counsel

5 [Kerry E. Maloney, Esquire, Board Counsel, welcomed
6 Acting Commissioner Johnson. Mr. Maloney noted Ian
7 Harlow to now be the Deputy Secretary for Regulatory
8 Programs.

9 Mr. Maloney stated the proposed regulations
10 regarding the authorization to administer injectables
11 was approved by the Governor's Budget Office and will
12 be discussed in executive session.

13 Mr. Maloney received comments from the Office of
14 General Counsel regarding compounding and will work on
15 the General Revisions.

16 Mr. Maloney noted the Commonwealth Court decision
17 on the Michael Kenney case, which will be discussed
18 during executive session.

19 Mr. Maloney addressed the Commonwealth Court
20 Mediation Program, which entails an outside party,
21 usually an attorney or judge, who will act as a
22 mediator. He stated it is nonbinding and is an
23 attempt to bring parties together to settle cases. He
24 explained the prosecution side, where the case is
25 mediated before it gets to the Board. He also

1 explained that on the counsel side, the mediation
2 program is set up initially by the Commonwealth Court,
3 only after the Board has issued a decision and the
4 licensee has appealed.]

5 ***

6 Report of Board Chairperson

7 [Terry Talbott, R.Ph., Chairperson, noted that she
8 will be the presenter at the 2019 Pennsylvania
9 Pharmacists Association (PPA) webinar on March 22,
10 2019. Board Counsel Maloney will review her
11 presentation.

12 Chairperson Talbott commented that the Board was
13 still awaiting Mark Zilner's re-nomination. She also
14 mentioned the need for two public members.

15 Mr. Maloney explained the new member process,
16 noting no public member was interested in the past
17 several months.

18 Mr. Johnson mentioned Stephen Latanishen, who was
19 formerly with the Governor's Office and worked
20 primarily in the area of nominations, was now with the
21 department. Mr. Johnson plans to utilize Mr.
22 Latanishen to address some of the delays.]

23 ***

24 Report of Probable Cause Screening Committee

25 [Patrick M. Greene, Esquire, Office of Attorney

1 General, signed a couple of Petitions for Mental and
2 Physical Examinations.]

3 ***

4 Report of Commissioner - No Report

5 ***

6 Report of Executive Secretary

7 [Melanie Zimmerman, R.Ph., Executive Secretary,
8 discussed her work on having the newsletter articles
9 reviewed, approved and then published.]

10 ***

11 New Business - iTEP's English Language Proficiency
12 Test

13 [Melanie Zimmerman, R.Ph., Executive Secretary, noted
14 a request from iTEP asking the Board to consider using
15 their English language proficiency exam. She
16 explained to iTEP that the Board requires graduates of
17 foreign pharmacy schools to have Foreign Pharmacy
18 Graduate Examination Committee (FPGEC) certification,
19 which already includes an English proficiency exam.

20 Chairperson Talbott commented that the Board
21 should continue with the exam used by the National
22 Association of Boards of Pharmacy as part of the FPGEC
23 certification process and should not offer another
24 test.

25 Chairperson Talbott requested that Ms. Zimmerman

1 send a note stating the Board was comfortable with the
2 current practices.]

3 ***

4 PSHP Sterile Compounding Education Summit
5 [Kerry E. Maloney, Esquire, Board Counsel, noted the
6 Pennsylvania Society of Health-System Pharmacists
7 (PSHP) Sterile Compounding Education Summit on April
8 26, 2019, in Hershey.]

9 ***

10 CHAIRPERSON TALBOTT:

11 Let's have a motion that we send Kerry,
12 Melanie, Janet, and Gayle; up to three
13 prosecutors; and any inspector who wants
14 to go to the PSHP Summit on compounding.

15 MS. HART:

16 So moved.

17 MR. FRANKIL:

18 Second.

19 CHAIRPERSON TALBOTT:

20 Any other discussion? All in favor? Any
21 opposed?

22 [The motion carried unanimously.]

23 ***

24 Proposed Amendments to NABP's Constitution and Bylaws
25 [Melanie Zimmerman, R.Ph., Executive Secretary,

1 questioned whether the Board would be interested in
2 proposing amendments to the National Association of
3 Boards of Pharmacy's constitution and bylaws.

4 Chairperson Talbott commented that the Board was
5 not interested.]

6 ***

7 Pharmacist's Concerns with Workload Issues

8 [Melanie Zimmerman, R.Ph., Executive Secretary,
9 referred to two emails received asking if the Board
10 could take action regarding the workload of
11 pharmacists and working conditions.

12 Dr. Cotchen noted similar letters received in the
13 past and previous discussions were that it would not
14 be the place of the Board to address this.

15 Ms. Hart commented that states are making
16 regulation much simpler. She stated Idaho reduced
17 their regulations to a minimal number of pages, noting
18 that the pharmacist was a responsible person who knows
19 what they can and cannot do and also noted the safety
20 of the public.

21 Mr. Frankil expressed his concerns with this
22 issue and suggested that the Board should address the
23 limitations. He noted that pharmacies are becoming
24 busier and more stressful. He commented on managing
25 his own workplace responsibly but was concerned with

1 people in corporate settings and other pharmacies who
2 do not have the ability to manage their own workplace.

3 Mr. Maloney referred to § 27.12 regarding
4 delegation to interns and techs. He suggested a
5 statement of policy, which would be a reminder to
6 practitioners that patient safety was the ultimate
7 goal and anything that detracts from that should
8 seriously be considered. He noted that this may not
9 technically be enforceable through prosecution but at
10 least sets up some guidelines for the regulated
11 community.

12 Mr. Frankil agreed with the development of a
13 statement of policy for some guidance. He suggested
14 making someone responsible for that policy but not the
15 pharmacist-in-charge.

16 Mr. Maloney mentioned that the language would be
17 drafted, where the pharmacist permit holder would be
18 responsible instead of the pharmacist manager or any
19 other individual.

20 Acting Commissioner Johnson questioned how this
21 would interplay with those states or situations where
22 there are actual statutory provisions for credentials
23 or regulated pharmacy techs. He also noted a pharmacy
24 technician bill, questioning what would happen if the
25 bill passes and if adopting regulations now may be

1 premature in light of having to promulgate
2 regulations.

3 Mr. Maloney commented on the statement of policy,
4 where there typically are not many comments or
5 pushback. He recommended looking at what other states
6 do and start a draft, noting that if something happens
7 to the bill, then the Board could backtrack with the
8 policy and move forward with the regulations required
9 under the bill.

10 Ms. Epple suggested the bill may not have been
11 introduced yet, but the intent was to introduce the
12 same one.]

13 ***

14 Annual NABP Meeting

15 [Terry Talbott, R.Ph., Chairperson, addressed the
16 Annual NABP Meeting May 16-18, 2019, in Minneapolis,
17 MN. She suggested giving Ms. Zimmerman as much notice
18 as possible for out-of-state travel.]

19 ***

20 CHAIRPERSON TALBOTT:

21 Janet was approved to go this week, so
22 now we need a motion to send Janet so
23 it's official.

24 DR. COTCHEN:

25 So moved.

1 MR. FRANKIL:

2 Second.

3 CHAIRPERSON TALBOTT:

4 Any other discussion? All in favor? Any
5 opposed?

6 [The motion carried unanimously.]

7 ***

8 For the Board's Information

9 [Terry Talbott, R.Ph., Chairperson, noted NABP
10 Executive Committee candidate information. She
11 mentioned that Caroline Juran, Executive Director,
12 Virginia Board of Pharmacy and Reggie Dillard,
13 Executive Director, Tennessee Board of Pharmacy, were
14 running for treasurer.

15 Chairperson Talbott also mentioned Cynthia
16 Warriner from Virginia and Tejal Patel from Delaware
17 for NABP Executive Committee positions.

18 Mr. Frankil addressed Narcan distribution. He
19 stated that companies get grants and distribute Narcan
20 to the communities or their employees. He noted
21 communication with PerformRx, noting that they are now
22 looking into getting grants to make it available for
23 their employees across the state.

24 Mr. Frankil questioned whether there would be
25 distribution outside of the pharmacy regulations and

1 whether there would be anything from the manufacturer
2 to distribute to their employees.

3 Mr. Frankil further explained that the company
4 got a grant to get it from the manufacturer, so the
5 manufacture will provide it to the company and then
6 the company will distribute it to its employees if
7 they want to have it available. He also noted that
8 training would be available.

9 Mr. Maloney commented that it is not done
10 pursuant to prescriptions. He also mentioned that the
11 new naloxone exception would not really apply because
12 it is not a prison or a treatment facility.

13 Mr. Frankil noted there would be no
14 recordkeeping, it is not patient-specific, and that
15 counties have been doing this for a long time now.

16 Mr. Maloney believed the Department of Health had
17 been distributing it through a healthcare provider,
18 meaning a physician who distributes it may dispense
19 under the physician's license. He noted that the
20 important question was who was distributing it.]

21

22 [Kathie Simpson, RN, Executive Director, Secundum
23 Artem Reaching Pharmacists with Help, informed the
24 Board that she will be retiring effective April 1 and
25 thanked the Board for all of their support.

1 Ms. Simpson stated Joann Megon will be replacing
2 her as the executive director.]

3 ***
4 [Pursuant to Section 708(a)(5) of the Sunshine Act, at
5 10 a.m., the Board entered into Executive Session with
6 Kerry E. Maloney, Esquire, Board Counsel, to receive
7 legal advice and engage in quasi-judicial
8 deliberations. Acting Commissioner Johnson exited the
9 meeting at 10:13 a.m. The Board returned to open
10 session at 11:39 a.m.]

11 ***

12 MOTIONS

13 CHAIRPERSON TALBOTT:

14 The Board of Pharmacy met in executive
15 session to discuss and review consent
16 orders and other legal documents.

17 Are there any motions concerning
18 those discussions?

19 DR. COTCHEN:

20 Madam Chairperson, I move that we approve
21 the Consent Agreement for File No. 18-54-
22 03100.

23 CHAIRPERSON TALBOTT:

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

25 MS. HART:

1 I move that we approve the Consent
2 Agreement for File No. 17-54-10065.

3 CHAIRPERSON TALBOTT:

4 Do we have a second?

5 MS. HART:

6 Second.

7 CHAIRPERSON TALBOTT:

8 Any discussion? Call the vote.

9

10 Frankil, aye; Greene, aye; Talbott, aye;
11 Cotchen, aye; and Hart, aye.

12 [The motion carried unanimously. The registrant's
13 name is Advanced Pharmacy LLC.]

14 ***

15 DR. COTCHEN:

16 I move that we reject the Consent
17 Agreement as too lenient for File No. 18-
18 54-010785.

19 CHAIRPERSON TALBOTT:

20 Do we have a second?

21 MS. HART:

22 Second.

23 CHAIRPERSON TALBOTT:

24 Any other discussion? Call the vote.

25

1 Frankil, aye; Greene, aye; Talbott, aye;
2 Cotchen, aye; and Hart, aye.

3 [The motion carried unanimously.]

4 ***

5 DR. COTCHEN:

6 I move that we draft and issue an
7 Adjudication and Order consistent with
8 executive session to grant a Petition to
9 Release from DMU, Michael G. Kenney,
10 Pharm.D., File No. 17-54-05554.

11 CHAIRPERSON TALBOTT:

12 Do we have a second?

13 MS. HART:

14 Second.

15 CHAIRPERSON TALBOTT:

16 Any discussion? Call the vote.

17

18 Frankil, aye; Greene, aye; Talbott, aye;
19 Cotchen, aye; and Hart, aye.

20 [The motion carried unanimously.]

21 ***

22 DR. COTCHEN:

23 I move that we adopt the proposed
24 Adjudication and Order for Woodland Hills
25 Pharmacy, File No. 18-54-006059.

1 MS. HART:

2 Second.

3 CHAIRPERSON TALBOTT:

4 Any discussion? Call the vote.

5

6 Frankil, aye; Greene, aye; Talbott, aye;

7 Cotchen, aye; and Hart, aye.

8 [The motion carried unanimously.]

9

10 DR. COTCHEN:

11 I move that we adopt the proposed

12 Adjudication and Order for NaphCare,

13 Inc., File No. 18-54-03894.

14 MS. HART:

15 Second.

16 CHAIRPERSON TALBOTT:

17 Any discussion? Call the vote.

18

19 Frankil, aye; Greene, aye; Talbott, aye;

20 Cotchen, aye; and Hart, aye.

21 [The motion carried unanimously. It was noted that

22 the applicant must comply with administrative

23 requirements.]

24

25 DR. COTCHEN:

1 I move that we adopt the proposed
2 Adjudication and Order for Vince E.
3 DeLuca, R.Ph., File No. 18-54-09350.

4 MS. HART:

5 Second.

6 CHAIRPERSON TALBOTT:

7 Any discussion? Call the vote.

8

9 Frankil, aye; Greene, aye; Talbott, aye;
10 Cotchen, aye; and Hart, aye.

11 [The motion carried unanimously.]

12

13 CHAIRPERSON TALBOTT:

14 Also, in executive session, we discussed
15 revisions to the Compounding Annex, so we
16 need a motion to approve those amendments
17 and any necessary adjustments to the
18 preamble so that Kerry could file it
19 before the April 10 deadline.

20 DR. COTCHEN:

21 So moved.

22 CHAIRPERSON TALBOTT:

23 Second?

24 MS. HART:

25 Second.

1 CHAIRPERSON TALBOTT:

2 All in favor? Any opposed?

3 [The motion carried unanimously.]

4 ***

5 [Kerry E. Maloney, Esquire, Board Counsel, stated
6 that changes to the annex remove sections already
7 addressed in the first section regarding compounding
8 being done in accordance with federal law and the USP.

9 He noted no substantive additions and no new
10 requirements that were not already there.]

11 ***

12 Adjournment

13 CHAIRPERSON TALBOTT:

14 Motion to adjourn.

15 DR. COTCHEN:

16 So moved.

17 [There was no second to the motion.]

18 ***

19 [There being no further business, the State Board of
20 Pharmacy Meeting adjourned at 11:44 a.m. A regulation
21 work session was held after the meeting.]

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CERTIFICATE

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



Seth R. Baier,
Minute Clerk
Sargent's Court Reporting
Service, Inc.

STATE BOARD OF PHARMACY
REFERENCE INDEX

March 5, 2019

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TIME	AGENDA
9:00	Official Call to Order
9:00	Pledge of Allegiance
9:01	Introduction of Board Members, Board Staff, and Audience Members
9:05	Approval of Minutes
9:06	Report of Prosecutorial Division
9:16	Appointment - Bureau of Finance and Operations Annual Budget Presentation
9:25	Report of Board Counsel
9:34	Report of Board Chairperson
9:34	Report of Committees
9:35	New Business
9:45	For the Board's Information
10:00	Executive Session
11:39	Return to Open Session
11:39	Motions
11:44	Adjournment