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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
MEETING CONDUCTED VIA TELECONFERENCE**

TIME: 11:35 A.M.

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

March 17, 2020

1 State Board of Pharmacy
2 March 17, 2020

3
4 BOARD MEMBERS:

- 5
6 Terry M. Talbott, R.Ph., Chairperson
7 K. Kalonji Johnson, Acting Commissioner of Bureau of
8 Professional and Occupational Affairs
9 Robert B. Frankil, R.Ph., Vice Chairperson
10 Janet Getzey Hart, R.Ph., Secretary
11 Patrick M. Greene, Esquire, Office of Attorney General
12 Thomas P. Carey, Ed.D. - Absent

13
14
15 BUREAU PERSONNEL:

- 16
17 Juan A. Ruiz, Esquire, Board Counsel
18 Ray Michalowski, Esquire, Board Prosecution Liaison
19 Carolyn A. DeLaurentis, Esquire, Deputy Chief Counsel,
20 Prosecution Division
21 Melanie Zimmerman, R.Ph., Executive Secretary
22 Ted Stauffer, Executive Secretary, Bureau of
23 Professional and Occupational Affairs

24
25 ALSO PRESENT:

- 26
27 Larry Jones, Executive Director, Pennsylvania Society
28 of Health-System Pharmacists
29 Leigh Shirley, Director of Pharmacy Operations, Giant
30 Food Stores
31 Patricia A. Epple, CEO, Pennsylvania Pharmacists
32 Association
33 Christine Renfer, CVS Health
34 Nichole Cover, Walgreens
35 Jim Reed, Walgreens
36 Jeffrey Sinko, CVS Health
37 Lauren Paul, Senior Director, Pharmacy Regulatory
38 Affairs, CVS Health
39 Carl Harting, CVS Health
40 Christine Roussel, Pharm.D., BCOP, Pennsylvania
41 Society of Health-System Pharmacists/Doylestown
42 Hospital
43 John Sisto, Express Scripts
44 Jenna L. McCarthy, Malady & Wooten
45 Lisa Scannapieco
46 Jessica Adams
47 Lawrence Caul

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State Board of Pharmacy

March 17, 2020

The regularly scheduled meeting of the State Board of Pharmacy was held via teleconference on Tuesday, March 17, 2020. Terry M. Talbott, R.Ph., Chairperson, called the meeting to order at 11:35 a.m.

[Chairperson Talbott requested the introduction of Board members, Board staff, and audience members.]

Approval of minutes of the January 28, 2020 meeting

CHAIRPERSON TALBOTT:

I would entertain a motion to approve the Board of Pharmacy minutes from the January 28th meeting.

MS. HART:

I'll make a motion.

CHAIRPERSON TALBOTT:

Second?

MR. FRANKIL:

Second.

CHAIRPERSON TALBOTT:

Rob will second. Any discussion on the

1 minutes? Hearing none, I'll obtain a
2 roll call vote.

3

4 Frankil, aye; Greene, aye; Johnson, aye;
5 Talbott, aye; and Hart aye.

6 [The motion carried unanimously.]

7

8 Report of Prosecutorial Division

9 [Chairperson Talbott recognized Prosecutorial Division
10 cases for discussion in Executive Session.

11 Carolyn DeLaurentis, Esquire, Deputy Chief
12 Counsel, Prosecution Division, stated, despite
13 operational shutdown due to COVID-19 concerns, the
14 majority of the Prosecution Division was working
15 remotely.]

16

17 Report of Board Counsel

18 [Juan A. Ruiz, Esquire, Board Counsel, noted two
19 proposed Adjudications and Orders as well as
20 applications for discussion during Executive Session.]

21

22 Report of Probable Cause Screening Committee

23 [Patrick M. Greene, Esquire, Office of Attorney
24 General, noted he signed a couple of Orders on
25 Petitions for Appropriate Relief.

1 Chairperson Talbott inquired as to how the
2 Prosecution Division would handle communications with
3 the committee. Mr. Michalowski noted communications
4 are typically conducted via email. There was
5 discussion regarding a possible backup plan, if
6 necessary.

7 Mr. Michalowski stated the division would receive
8 communications through the pa.gov email.]

9 ***

10 Report of Executive Secretary

11 [Melanie Zimmerman, R.Ph., Executive Secretary, noted,
12 although Board offices are closed, staff are working
13 remotely and will continue to process applications.
14 Communications are being conducted through email, as
15 the phone system is unavailable. Given the expected
16 increase in the number of e-mails, there may be delays
17 in responding to the e-mails.

18 Chairperson Talbott asked whether dedicated staff
19 was working on applications upon receipt. Ms.
20 Zimmerman explained that each staff member is assigned
21 specific applications. She noted the staff will be
22 working on existing applications as well as new
23 applications.]

24 ***

25 New Business

1 [Chairperson Talbott noted there were no names to put
2 in for the National Association of Boards of Pharmacy
3 (NABP) Recognition Resolution as no one passed away in
4 the past year.

5 Ms. Zimmerman updated the Board regarding the NABP
6 Annual meeting Scheduled for May 14-16, 2020. An out-
7 of-state travel ban is currently in place. She noted
8 Ms. Hart had been selected as the Board's voting
9 delegate and Chairperson Talbott is listed as the
10 alternate voting delegate.]

11 ***

12 Old Business

13 [The Board discussed school rotation sites at
14 marijuana dispensaries. Chairperson Talbott had
15 requested that Ms. Zimmerman seek information from the
16 Accreditation Council for Pharmacy Education (ACPE) on
17 the acceptability of marijuana dispensaries as
18 internship sites. While ACPE does not require
19 internship sites to be licensed pharmacies, the
20 internship sites must comply with state laws and
21 regulations.

22 Chairperson Talbott noted the Board does not
23 regulate marijuana dispensaries in Pennsylvania. She
24 noted schools are looking for guidance as they
25 organize rotations for the next year. Ms. Zimmerman

1 commented there are many out-of-state applicants, and
2 the Board is unaware of the practices of schools in
3 other states. Chairperson Talbott concurred, noting
4 in some states the Board of Pharmacy does oversee the
5 marijuana dispensaries.

6 Ms. Hart reminded the Board that regulations in
7 Pennsylvania mandate there be a pharmacist or another
8 health care provider/prescriber at the dispensary, so
9 she supported allowing the hours.

10 Mr. Frankil was not in favor of allowing the hours
11 since dispensaries are not overseen by the Board and
12 the Board does not have any control over them. Ms.
13 Hart countered that dispensaries are actually more
14 regulated than pharmacies. Mr. Frankil agreed but
15 reiterated his opinion.

16 There was further discussion regarding other
17 entities whose education hours are accepted, despite a
18 lack of regulation by the Board of Pharmacy, including
19 Indian reservations and insurance companies.

20 Mr. Ruiz quoted Regulation 27.26 (e), "The Board
21 will grant internship credit only for activities
22 related to the practice of pharmacy. The following
23 are examples of these activities: Scrutinizing
24 prescriptions or drug orders, taking oral orders for
25 prescriptions by telephone or otherwise, compounding

1 medications and filling prescriptions. The Board will
2 not grant internship credit for activities which are
3 not related to the practice of pharmacy."

4 He noted the question deals with defining the
5 practice of pharmacy. He cautioned, from a legal
6 standpoint, working at a dispensary was not considered
7 the practice of pharmacy.

8 There was discussion regarding so-called non-
9 pharmacy externships, such as those at dispensaries,
10 and whether students would fall below the 1500 intern
11 hours requirement if the hours earned at these sites
12 did not count towards licensure.

13 Ms. Hart pointed out the Medical Marijuana Program
14 recently issued licenses for various schools, such as
15 LECOM, to work with dispensaries on research and
16 development. Some schools were now working with the
17 dispensaries, growers and processors.

18 Chairperson Talbott suggested continuing the
19 discussion on the matter at the Board's May meeting.
20 She asked Ms. Zimmerman to reach out to LECOM for
21 information.

22 Chairperson Talbott asked Mr. Michalowski about
23 contacts with the Medical Marijuana Board. Mr.
24 Michalowski noted he did have contact with the Medical
25 Marijuana Board and the Board of Pharmacy may want to

1 consider inviting a representative from the Department
2 of Health (DOH) to speak to the Board of Pharmacy.

3 Mr. Michalowski also noted, since dispensaries can
4 be overseen clinically either by a physician,
5 osteopath or pharmacist, there may be the possibility
6 to require students to perform their hours in the
7 presence of a pharmacist.

8 A consensus was reached to revisit the issue in
9 May for further discussion under old business and also
10 to obtain additional information.]

11 ***

12 Report of Acting Commissioner

13 [K. Kalonji Johnson, Acting Commissioner of the Bureau
14 of Professional and Occupational Affairs, reported on
15 BPOA's extensive work with the Department of Health
16 and the Policy Office to ensure the waivers under the
17 Governor's emergency declaration are implemented
18 smoothly.

19 He emphasized, although there was an impact on
20 operations due to availability of resources,
21 applications are still being processed by the majority
22 of staff, who are working from home.

23 Chairperson Talbott stated the people in the
24 pharmacy industry have reached out to her with
25 questions regarding patient safety, what to do if

1 somebody is exposed to coronavirus, and how to social
2 distance at a mail site.

3 She noted the Board may not be able to issue
4 guidance on waivers or issue blanket statements, but
5 opined there should be an announcement to the
6 community. As an example, there was an inquiry as to
7 waiving enforcement of USP 797 due to the current
8 shortage of personal protective equipment (PPE).

9 Chairperson Talbott inquired of Commissioner
10 Johnson as to the information the Board may offer to
11 provide guidance to the individuals who are asking
12 questions. Mr. Johnson expressed a concern about
13 making blanket waivers, noting most of the Board's
14 functions are discretionary and reviewed on a case-by-
15 case basis in determining whether discipline is
16 appropriate or a certain action may have been
17 justified. He asserted, if there was a process in
18 place for exceptions, protections would be built into
19 that process and suggested a wait-and-see approach.

20 Mr. Michalowski noted he had dealt with similar
21 questions even before COVID-19 with inspectors. He
22 stated inspectors often ask if new practices are a
23 violation and the regulations are reviewed. He used
24 the example of compounding regulations and noted there
25 was some flexibility to allow for performing different

1 methods within the regulations.

2 Mr. Michalowski referred to the opioid disaster
3 declaration, noting there were waivers regarding the
4 use of naloxone before any regulatory change was made.
5 He stated any waivers would have to be granted in a
6 very specific way at the Governor's discretion.

7 Chairperson Talbott referred to the Board's
8 compounding regulations at 27.601 regarding sterile
9 and non-sterile preparations. She noted USP and CDC
10 were working with PPE manufacturers. She questioned
11 whether enforcement could be waived temporarily.

12 Mr. Ruiz warned against making blanket waivers,
13 asserting regulations were to protect both patient and
14 practitioner safety. He indicated there may be more
15 discussion if the situation worsens.

16 Chairperson Talbott noted it may be necessary to
17 have an emergency meeting of the Board to take a look
18 at specific regulations that may need to be waived.

19 Mr. Ruiz assured the Board he would pass any Board
20 waiver request on to the Commissioner.

21 Mr. Johnson suggested placing the Pharmacy
22 Application Review Committee in charge of identifying
23 key elements that can be waived.]

24 ***

25 New Business

1 [Chairperson Talbott shared correspondence from
2 Walgreens, which is evaluating current contingency
3 plans in the event of an outbreak of COVID-19 in one
4 of the facilities. She noted the company does not
5 currently allow pharmacists to access their system to
6 conduct data entry or pharmacist verification from a
7 remote location.

8 Chairperson Talbott stated this was not prohibited
9 in the statute or regulation.

10 There was a discussion regarding Walgreens'
11 question with regard to technicians. Chairperson
12 Talbott noted the statute calls for the direct,
13 immediate, personal supervision of technicians by a
14 pharmacist, which might limit remote work that can be
15 performed by technicians.

16 Mr. Michalowski opined that it would likely be
17 acceptable for technicians to perform remote data
18 entry that could be verified by the pharmacist. He
19 cautioned, when physically filling prescriptions,
20 there would need to be direct supervision.

21 Chairperson Talbott noted the need for further
22 discussion in the future.

23 Commissioner Johnson encouraged the Board to
24 provide him with input that he may pass on to state
25 policy makers.

1 There was discussion regarding when it would be
 2 appropriate for a pharmacy to report a non-permanent
 3 closure to the Board. Mr. Johnson noted that it makes
 4 sense to notify the Board if a business would be
 5 closed for an extended period of time, but encouraged
 6 pharmacies to implement plans on how to manage hygiene
 7 first. He noted any proposed procedures should be
 8 reported to the Governor's Policy Office so guidance
 9 could be issued.

10 Mr. Frankil noted the pharmacy boards in New
 11 Jersey and Ohio have sent out notices on how to deal
 12 with certain situations, and Pennsylvania should do
 13 the same ASAP.

14 Chairperson Talbott suggested compiling a list of
 15 possible waivers during Executive Session.

16 Mr. Michalowski stressed the importance of
 17 pharmacies notifying customers about closures. He
 18 noted customers should have information as to how long
 19 a facility would be closed, any transfers to other
 20 pharmacies via a sign on their door, on their phone
 21 lines or email. He suggested guidelines for
 22 pharmacies that are closing for more than four hours.]

23 ***

24 Audience Member Comments

25 [Ms. Roussel addressed USP 797, noting it allows for

1 the reuse of gowns in a shift, but not masks.
2 She mentioned facilities also go through sterile
3 gloves quickly. She expressed a concern for these
4 items being thrown away with the current shortage.
5 She also noted gloves can be sterilized using alcohol
6 and asked for guidance on alternative methods for
7 using PPE.

8 Mr. Jones pointed out the industry was not
9 expecting waivers on basics, such as training, checks
10 and balances, labeling, and a pharmacist's
11 supervision.

12 Ms. Roussel reminded the Board of the updated USP
13 800, which requires non-sterile compounders to wear
14 N95 respirators for certain activities.

15 Ms. Paul, CVS, thanked the Board for the
16 discussion. She reiterated the need to act quickly to
17 provide guidance in the pharmacy community. Ms. Paul
18 requested clear direction on the status of
19 technicians. She noted CVS has two very large
20 pharmacies in Pennsylvania. Ms. Paul requested
21 guidance on enforcement waivers or other processes as
22 soon as possible.

23 Ms. Cover noted there are 51 different state
24 boards trying to enforce regulations in a unique
25 situation.

1 Ms. Epple urged the Board provide guidance as soon
2 as possible.

3 Mr. Sisto reiterated that when technicians work
4 remotely there is electronic supervision. He noted it
5 would be helpful to take a large population out of the
6 pharmacy. He stated it would also leave a smaller
7 footprint of people in the pharmacy to perform
8 dispensing functions, which would reduce their
9 exposure.

10 Chairperson Talbott questioned the number of
11 people working at some of the pharmacy sites. Mr.
12 Sisto estimated between two sites at least 400 to 500
13 people. Ms. Cover estimated at least 200 to 300
14 people. Ms. Renfer stated close to 700 in Wilkes-
15 Barre and approximately 500 in Pittsburgh.

16 Mr. Sinko opined that the question regarding
17 technicians did not need to go through a waiver. He
18 noted electronic supervision of data entry was common.

19 Mr. Sinko urged the Board to make a prompt decision.

20 Chairperson Talbott noted that Mr. Sinko sits on
21 the New Jersey Board of Pharmacy.]

22 ***

23 [Pursuant to Section 708(a)(5) of the Sunshine Act, at
24 12:47 p.m. the Board entered into Executive Session
25 with Juan A. Ruiz, Esquire, Board Counsel, for the

1 purpose of conducting quasi-judicial deliberations.

2 The Board returned to open session at 1:28 p.m.]

3 ***

4 MOTIONS:

5 CHAIRPERSON TALBOTT:

6 The Board of Pharmacy met in Executive
7 Session.

8 Were there any and are there any
9 motions?

10 MR. GREENE:

11 I make the motion that we approve the
12 Consent Agreement at Case No. 19-54-
13 015527.

14 CHAIRPERSON TALBOTT:

15 Second?

16 MR. FRANKIL:

17 Frankil, second.

18 CHAIRPERSON TALBOTT:

19 Any discussion? Call the vote.

20

21 Frankil, aye; Greene, aye; Johnson, aye;

22 Talbott, aye; and Hart, aye.

23 [The motion carried unanimously. The Respondent's
24 name is James F. Franks, R.Ph.]

25 ***

1 MR. GREENE:

2 I make the motion that we approve the
3 Consent Agreement at Case No. 16-54-10954

4 CHAIRPERSON TALBOTT:

5 Do we have a second?

6 MR. FRANKIL:

7 Frankil second.

8 CHAIRPERSON TALBOTT:

9 Any discussion? Call the vote.

10

11 Frankil, aye; Greene, aye; Johnson, aye;
12 Talbott, aye; and Hart, aye.

13 [The motion carried unanimously. The Respondent's
14 name is Erich J. Cushey, R.Ph.]

15 ***

16 MR. GREENE:

17 I make the motion that we approve the
18 Consent Agreement at Case No. 18-54-
19 02779.

20 MR. FRANKIL:

21 Frankil second.

22 CHAIRPERSON TALBOTT:

23 Any discussion? Call the vote.

24

25 Frankil, aye; Greene, aye; Johnson, aye;

1 Talbott, aye; and Hart, aye.

2 [The motion carried unanimously. The Respondent's
3 name is Denise Clare Racano, R.Ph.]

4 ***

5 MR. GREENE:

6 I make the motion that we approve the
7 Consent Agreement at Case No. 19-54-
8 008580.

9 MR. FRANKIL:

10 Frankil second.

11 CHAIRPERSON TALBOTT:

12 Any discussion? Call the vote.

13

14 Frankil, aye; Greene, aye; Johnson, aye;
15 Talbott, aye; and Hart, aye.

16 [The motion carried unanimously. The Respondent's
17 name is Drugs Are Us, Inc. t/d/b/a Hopewell Pharmacy.]

18 ***

19 MR. GREENE:

20 I make the motion that we approve the
21 Consent Agreement at Case No. 19-54-
22 014931.

23 MR. FRANKIL:

24 Frankil second.

25 CHAIRPERSON TALBOTT:

1 Any discussion? Call the vote.

2

3 Frankil, aye; Greene, aye; Johnson, aye;

4 Talbott, aye; and Hart, aye.

5 [The motion carried unanimously. The Respondent's
6 name is Robert Patrick Osborne, R.Ph.]

7

8 MR. FRANKIL:

9 I make the motion to approve File No.

10 19-54-016424.

11 MS. HART:

12 Hart second.

13 CHAIRPERSON TALBOTT:

14 Any discussion? Call the vote.

15

16 Frankil, aye; Greene, recuse; Johnson,

17 aye; Talbott, aye; and Hart, aye.

18 [The motion carried. Mr. Greene recused himself from
19 deliberations and voting on the motion. The
20 Respondent's name is Steven Paul Teti, R.Ph.]

21

22 MR. FRANKIL:

23 I make the motion to approve File No. 19-

24 54-016425.

25 CHAIRPERSON TALBOTT:

1 Do we have a second?

2 MS. HART:

3 Hart second.

4 CHAIRPERSON TALBOTT:

5 Any discussion? Call the vote.

6

7 Frankil, aye; Greene, recuse; Johnson,
8 aye; Talbott, aye; and Hart, aye.

9 [The motion carried. Mr. Greene recused himself from
10 deliberations and voting on the motion. The
11 Respondent's name is Amy Jill Zandonella, R.Ph.]

12 ***

13 MR. GREENE:

14 I make the motion that we approve the
15 Consent Agreement at Case No. 18-54-
16 012272 and 18-54-012271.

17 CHAIRPERSON TALBOTT:

18 Janet, you may have to second this one.

19 MS. HART:

20 Hart second.

21 CHAIRPERSON TALBOTT:

22 Any discussion? Call the vote.

23

24 Frankil, recuse; Greene, aye; Johnson,
25 aye; Talbott, aye; and Hart, aye.

1 [The motion carried. Mr. Frankil recused himself from
2 deliberations and voting on the motion. The
3 Respondent's name is Bethany L. Miller, R.Ph., and
4 Lion Pharmacy.]

5 ***

6 MR. GREENE:

7 I make the motion that we approve the
8 following VRP Consent Agreements at Case
9 No. 19-54-018633 and Case No. 19-54-
10 012387.

11 MS. HART:

12 Hart, second.

13 CHAIRPERSON TALBOTT:

14 Any discussion? Call the vote.

15

16 Frankil, aye; Greene, aye; Johnson, aye;
17 Talbott, aye; and Hart, aye.

18 [The motion carried unanimously.]

19

20 MR. GREENE:

21 I make the motion that we approve the
22 Consent Agreement at Case No. 19-54-
23 017033.

24 MR. FRANKIL:

25 Frankil second.

1 CHAIRPERSON TALBOTT:

2 Any discussion? Call the vote.

3

4 Frankil, aye; Greene, aye; Johnson, aye;

5 Talbott, aye; and Hart, aye.

6 [The motion carried unanimously. The Respondent's
7 name is Amanda Crowe, R.Ph.]

8

9 MR. GREENE:

10 I make the motion that we approve the
11 Consent Agreement at Case No. 20-54-
12 000618.

13 MR. FRANKIL:

14 Frankil second.

15 CHAIRPERSON TALBOTT:

16 Any discussion? Call the vote.

17 Frankil, aye; Greene, aye; Johnson, aye;

18 Talbott, aye; and Hart, aye.

19 [The motion carried unanimously. The Respondent's
20 name is Gerald S. Effland, Jr., R.Ph.]

21

22 [The Final Adjudication and Order in the matter of
23 BPOA vs. James Conrad Burke, R.Ph., Case Nos. 15-54-
24 01250 and 15-54-00537, was tabled due to lack of a
25 quorum.]

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MR. GREENE:

I make a motion that we adopt the Final Adjudication and Order in the matter of BPOA vs. Gino S. Cordisco, R.Ph., Case Nos. 15-54-01804 and 17-54-11497.

MR. FRANKIL:

Frankil second.

CHAIRPERSON TALBOTT:

Any discussion? Call the vote.

Frankil, aye; Greene, aye; Johnson, aye; Talbott, aye; and Hart, aye.

[The motion carried unanimously.]

MR. GREENE:

I make a motion that we conditionally approve the application of Metro Care Pharmacy, pending receipt of information requested by the Board.

MR. FRANKIL:

Frankil second.

CHAIRPERSON TALBOTT:

Any discussion? Call the vote.

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

3 [The motion carried unanimously.]

4 ***

5 [The application of Carepharm Pharmacy, LTC, was
6 tabled.]

7 ***

8 [Chairman Talbott announced that the regulatory
9 Committee would meet on March 18, 2020, to review the
10 regulations that may need to be waived due to the
11 pandemic situation.]

12 ***

13 Adjournment

14 CHAIRPERSON TALBOTT:

15 I will entertain a motion to adjourn and
16 practice good social distance.

17 MS. HART:

18 So moved.

19 MR. JOHNSON:

20 Second.

21 ***

22 [Mr. Johnson thanked the Board for their discussion of
23 the pandemic situation.]

24 ***

25 [There being no further business, the State Board of

1 Pharmacy Meeting was adjourned at 1:41 p.m.]

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CERTIFICATE

I hereby certify that the foregoing summary minutes of the State Board of Pharmacy, 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.



Alicia Gascoigne,

Minute Clerk

Sargent's Court Reporting
Service, Inc.

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STATE BOARD OF PHARMACY
REFERENCE INDEX
March 17, 2020

TIME	AGENDA
11:35	Official Call to Order
11:36	Roll Call and Audience Members Introduced
11:40	Adoption of Minutes
11:42	Report of Prosecutorial Division
11:44	Report of Board Counsel
11:45	Report of Probable Cause Screening Committee
11:46	Report of Executive Secretary
11:48	New Business
11:59	Old Business
12:03	Report of Commissioner and Report of Board Chairperson
12:30	Audience Member Comments
12:47	Executive Session
1:28	Return from Executive Session
1:28	Motions
1:41	Adjournment