

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

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
VIA VIDEOCONFERENCE**

TIME: 10:33 A.M.

PENNSYLVANIA DEPARTMENT OF STATE

March 17, 2021

State Board of Pharmacy
March 17, 2021

ALSO PRESENT: (Continued)

1
2
3
4
5
6
7 Christine Renfer, Pharm.D., Director of Professional
8 Practices & Pharmacist in Charge, CVS/Caremark
9 Pharmacy
10 David Klinger, System Director, Operations
11 & Compliance, Geisinger Health System
12 Dennis DiGiorno
13 Hailey Mook, Pharmacy Intern, Pennsylvania
14 Pharmacists Association
15 Jacquelyn Sassaman, Pentec Health
16 Jenna McCarthy, Malady & Wooten, on behalf of PA CVS
17 Jim Reed, Health Outcomes Supervisor/Strategic
18 Partnerships Leader, Walgreens
19 John Sisto, Senior Director of Regulatory Affairs,
20 Express Scripts
21 Joshua Finger, Enclara Pharmacia
22 Judy Kutchman, AllianceRx Walgreens Prime
23 Larry Jones, Executive Director, Pennsylvania
24 Society of Health-System Pharmacists
25 Leigh Shirley, Giant Pharmacy
26 Lisa Scannapieco, Director of Pharmacy Education and
27 Clinical Integration, Pentec Health
28 Nicole Corbett, Pharmacy Technician, Walgreens
29 Rhea Angeles, Pharm.D., Executive Fellow, Pharmacy
30 Technician Certification Board
31 Robert Kistler, Pharm.D.
32 Ryan Burke, Pharm.D., Director of Professional
33 Affairs, Pharmacy Technician Certification Board
34 Steve Sheaffer, Pharm.D., Pennsylvania Society of
35 Health-System Pharmacists
36 Steven Zahn, Pharmacy Inspector, Bureau of Enforcement
37 and Investigation, Department of State
38 Tamara Walker
39 Victoria Elliott, RPh, MBA, CAE, CEO, Pennsylvania
40 Pharmacists Association
41 Walter Valentine, Enclara Pharmacia
42 Catherine Lutz, Pharmacy Inspector, Bureau of
43 Enforcement and Investigation, Department of State
44 Jessica Zukoski
45 Jay Panyam
46 Jack Korbutov
47 Andrew Harvan
48 Nichole Cover
49 Laura Romeo
50

State Board of Pharmacy
March 17, 2021

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50

ALSO PRESENT: (Continued)

Kevin Hoffman
Jason Anderson
Derek Richmond

1 ***

2 State Board of Pharmacy

3 March 17, 2021

4 ***

5 [Pursuant to Section 708(a)(5) of the Sunshine Act, at
6 9:00 a.m., the Board entered into Executive Session
7 with Juan A. Ruiz, Esquire, Board Counsel, to receive
8 legal advice and engage in quasi-judicial
9 deliberations. The Board returned to open session at
10 10:30 a.m.]

11 ***

12 [Theodore Stauffer, Executive Secretary, Bureau of
13 Professional and Occupational Affairs, noted the
14 meeting was being recorded, and those who remained on
15 the line were giving their consent to be recorded.]

16 ***

17 The regularly scheduled meeting of the State
18 Board of Pharmacy was held on Wednesday, March 17,
19 2021. Janet Getzey Hart, R.Ph., Chairperson, called
20 the meeting to order at 10:33 a.m.

21 K. Kalonji Johnson, Commissioner, Bureau of
22 Professional and Occupational Affairs, was not present
23 at the commencement of the meeting.

24 ***

25 Introduction of the Board Members

1 [Chairperson Hart requested Board members and staff
2 introduce themselves.]

3 ***

4 [Juan A. Ruiz, Esquire, Board Counsel, introduced
5 legal intern, Travis Murray, with the Counsel
6 Division.]

7 ***

8 Approval of Minutes

9 CHAIRPERSON HART:

10 The first item is approval of the meeting
11 minutes from December 1, 2020.

12 MS. TALBOTT:

13 I'll make a motion to approve the minutes
14 from both December and January. We can
15 do them both together.

16 CHAIRPERSON HART:

17 Do I have a second?

18 MR. FRANKIL:

19 Second.

20 CHAIRPERSON HART:

21 Any discussion? Those who approve, all
22 say aye.

23 [The motion carried unanimously.]

24 ***

25 Report of Prosecutorial Division

1 [Alice Glasser, Esquire, Board Prosecutor, presented
2 the Consent Agreement for Case No. 20-54-013683.]

3 ***

4 [Ray Michalowski, Esquire, Senior Board Prosecution
5 Liaison, presented the VRP Consent Agreements for VRP
6 Case No. 21-54-000230 and VRP Case No. 21-54-000028.]

7 ***

8 [Steven A. Mimm, Esquire, Board Prosecutor, presented
9 the Consent Agreement for Case No. 17-54-11129.

10 Wesley J. Rish, Esquire, Rish Law Office, LLC,
11 Counsel for the Respondent, was present.]

12 ***

13 Report of Board Counsel

14 [Juan A. Ruiz, Esquire, Board Counsel, noted the Board
15 met in Executive Session prior to the start of this
16 meeting and discussed two proposed Adjudications and
17 Orders on the agenda. He also informed the Board of
18 the outcome of the order dismissing the case in Lasher
19 v. State Board of Pharmacy. He also noted discussion
20 regarding a Motion to Deem Facts Admitted and Enter
21 Default.

22 Mr. Ruiz informed the Board of a presentation
23 scheduled for 11 a.m. from the National Association of
24 Boards of Pharmacy (NABP) concerning the Food and Drug
25 Administration's (FDA) Memorandum of Understanding

1 (MOU) and their information-sharing project.

2 Mr. Ruiz noted a regulation work session to begin
3 discussions on the pharmacy technician regulations
4 after the Board meeting.

5 Chairperson Hart noted recusal guidelines for the
6 Board's Review.]

7 ***

8 Report of Board Chair

9 [Janet Getzey Hart, R.Ph., Chairperson, thanked Ms.
10 Talbott for providing a presentation on Board updates
11 to the Pennsylvania Pharmacists Association and
12 receiving high reviews.

13 Ms. Talbott noted being pleased with the
14 attendance of 55 people at the presentation. She
15 mentioned there was discussion regarding waivers.

16 Mr. Frankil also mentioned there was a review of
17 the regulatory process and the lengthy timeframe until
18 final publication.

19 Chairperson Hart informed the Board that she
20 received a letter from the National Association of
21 Chain Drug Stores (NACDS) asking for a temporary
22 waiver to remove duplicative notification requirements
23 for the COVID-19 vaccine. She confirmed receipt of
24 the request and noted that the letter will be
25 considered.]

1 ***

2 Report of Probable Cause Screening Committee
3 [Patrick M. Greene, Esquire, Office of Attorney
4 General, noted signing one Order on a Petition to
5 Compel a Mental and Physical Examination since the
6 last meeting.]

7 ***

8 Report of Executive Secretary
9 [Melanie Zimmerman, R.Ph., Executive Secretary,
10 reported there have been 298 authorizations issued to
11 pharmacy interns to administer injectables.

12 Ms. Talbott questioned whether there had been
13 information sent to the schools, noting the goal of
14 starting to transition from the COVID-19-related
15 letter of intent to applying for the permanent
16 authorization to administer injectables.

17 Ms. Zimmerman addressed the two-year time frame
18 for the education, stating that those with a valid
19 training program would want to apply for a permanent
20 authorization now, but for the individuals whose
21 training program is expired, they are going to have to
22 repeat the training program.

23 Mr. Ruiz commented that Ms. Zimmerman could send
24 an email notifying the schools that applications for
25 the pharmacy intern's authorization to administer are

1 available.]

2

3 New Business

4 [Janet Getzey Hart, R.Ph., Chairperson, noted the
5 117th Annual National Association of Boards of
6 Pharmacy (NABP) Meeting scheduled for May 13-14, 2021.

7 She noted that the Board did not have a poster
8 proposal to submit and mentioned a question concerning
9 proposed amendments to the NABP constitution and
10 bylaws, stating the Board did not have any.]

11 CHAIRPERSON HART:

12 Do I have any proposals for attendance at
13 that meeting?

14 MS. TALBOTT:

15 I will make the motion that we send you,
16 Janet Hart, as our delegate and Christine
17 Roussel as our alternate delegate, and
18 Melanie can file all the paperwork and
19 hopefully grant to allow you to attend
20 the virtual meeting.

21 MR. FRANKIL:

22 I will second that motion.

23 CHAIRPERSON HART:

24 Any discussion? All in favor, aye?

25 [The motion carried unanimously.]

1 ***

2 CHAIRPERSON HART:

3 The other item on the agenda is the
4 October 26-27 FDA Intergovernmental
5 Working Meeting on Drug Compounding.

6 Do I have any motions concerning
7 that?

8 MS. TALBOTT:

9 I will make the motion that we send
10 Christine, either virtually or hopefully
11 in person to that meeting and that she
12 work with Melanie as we get more
13 information.

14 MR. FRANKIL:

15 Second.

16 CHAIRPERSON HART:

17 Any discussion? All in favor, aye?
18 Opposed?

19 [The motion carried unanimously.]

20 ***

21 MOTIONS

22 CHAIRPERSON HART:

23 The Board of Pharmacy met in Executive
24 Session to discuss and review consent
25 orders and other legal documents. Are

1 there any motions regarding these
2 discussions?

3 MR. GREENE:

4 I make a motion that we approve the
5 Consent Agreement at Case No. 20-54-
6 013683.

7 MR. FRANKIL:

8 Second.

9 CHAIRPERSON HART:

10 Call for discussion? Call for a vote.

11

12 Talbott, aye; Roussel, aye; Frankil, aye;
13 Greene, aye; Stauffer, aye; Hart aye.

14 [The motion carried unanimously. The Respondent's
15 name is Joseph Michael Martella, R.Ph.]

16

17 MR. GREENE:

18 On agenda items 4 and 5, I make the
19 motion that we approve the VRP Consent
20 Agreements at Case No. 21-54-000230 and
21 Case No. 21-54-000028.

22 MR. FRANKIL:

23 Second.

24 CHAIRPERSON HART:

25 Call for discussion? Call for a vote.

1

2

Talbott, aye; Roussel, aye; Frankil, aye;

3

Greene, aye; Stauffer, aye; Hart aye.

4

[The motion carried unanimously.]

5

6

MR. GREENE:

7

On agenda item 6, I make the motion that

8

we approve the Consent Agreement at Case

9

No. 17-54-11129.

10

MR. FRANKIL:

11

Second.

12

CHAIRPERSON HART:

13

Call for discussion? Call for a vote.

14

15

Talbott, aye; Roussel, aye; Frankil, aye;

16

Greene, aye; Stauffer, aye; Hart aye.

17

[The motion carried unanimously. The Respondent's

18

name is Eric John Miladin, R.Ph.]

19

20

MR. GREENE:

21

On agenda item 7, I make the motion that

22

we direct Board Counsel to draft an

23

Adjudication and Order consistent with

24

discussions held in Executive Session for

25

Peter J. Antinopoulos, R.Ph., Case No.

1 19-54-018123.

2 MR. FRANKIL:

3 Second.

4 CHAIRPERSON HART:

5 Call for discussion? Call for a vote.

6

7 Talbott, aye; Roussel, aye; Frankil, aye;

8 Greene, aye; Stauffer, aye; Hart aye.

9 [The motion carried unanimously.]

10 ***

11 MR. GREENE:

12 On agenda item 8, I make a motion that we

13 direct Board Counsel to draft an

14 Adjudication and Order consistent with

15 discussions in Executive Session for

16 Jacient D. Bray, R.Ph., Case No. 20-54-

17 009518.

18 MR. FRANKIL:

19 Second.

20 CHAIRPERSON HART:

21 Call for discussion? Call for a vote.

22

23 Talbott, aye; Frankil, aye; Greene, aye;

24 Stauffer, aye; Roussel, aye; Hart aye.

25 [The motion carried unanimously.]

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

MR. GREENE:

On agenda item 12, I make a motion that we provisionally deny the Nonresident Pharmacy Application of Guardian Pharmacy of Virginia, LLC.

MR. FRANKIL:

Second.

CHAIRPERSON HART:

Call for discussion? Call for a vote.

Talbott, aye; Roussel, aye; Frankil, aye; Greene, aye; Stauffer, aye; Hart aye.

[The motion carried unanimously.]

MR. GREENE:

On agenda item 13, the matter of the Application of Francis McCabe.

I make a motion that we approve the Authorization to Administer Injectables.

MR. FRANKIL:

Second.

CHAIRPERSON HART:

Any discussion? Call for a vote.

1 Talbott, aye; Roussel, aye; Frankil, aye;
2 Greene, aye; Stauffer, aye; Hart aye.

3 [The motion carried unanimously.]

4 ***

5 MR. GREENE:

6 On agenda item 14, I make a motion that
7 we approve the Reciprocal Licensure
8 Application of Muhammad Alislambouli.

9 MR. FRANKIL:

10 Second.

11 CHAIRPERSON HART:

12 Call for discussion? Call for a vote.

13

14 Talbott, aye; Roussel, aye; Frankil, aye;
15 Greene, aye; Stauffer, aye; Hart aye.

16 [The motion carried unanimously.]

17 ***

18 MR. RUIZ:

19 Is there a motion to grant the Motion to
20 Deem Facts Admitted and Enter Default in
21 the case of Family Pharmacy, Case No. 18-
22 54-009040?

23 MS. TALBOTT:

24 I make the motion.

25 MR. FRANKIL:

1 Second.

2

3 Call for discussion. Call for a vote.

4

5 Talbot, aye; Roussel, aye; Frankil, aye;

6 Greene, aye; Stauffer, aye; Hart aye.

7 [The motion carried unanimously.]

8

9 [Terry M. Talbott, R.Ph., requested information
10 regarding the revisions to the intern regulations.]

11 Mr. Ruiz noted making changes to the annex and
12 currently working on the preamble with the goal of
13 completing the regulations before summer.]

14

15 Appointment - FDA's MOU and NABP's Compounding

16 Pharmacy Information-Sharing Project

17 [Melissa Madigan, Pharm.D., J.D., Associate Executive
18 Director of Professional Affairs, National Association
19 of Boards of Pharmacy, mentioned receiving dozens of
20 questions regarding the MOU.]

21 Dr. Madigan referred to one of the questions
22 regarding whether the FDA would delay enforcement of
23 the 5% rule, which would be enforced in October, one
24 year after the release of the MOU. She had not
25 received an answer, but the FDA was saying no at this

1 point.

2 Dr. Madigan stated boards wanted to know what
3 information is required to be provided to the FDA.
4 She noted the boards are obligated to provide
5 compounding information and data, complaints related
6 to compounding pharmacies, complaints concerning
7 compounding physicians, and information regarding
8 compounding physicians who are distributing
9 interstate.

10 Dr. Madigan explained that the Board would have
11 to provide information concerning pharmacies that are
12 compounding human drug products and distributing
13 inordinate amounts interstate, including their
14 compounding data, when submitting information
15 regarding a pharmacy.

16 Dr. Madigan stated the boards are obligated to
17 submit information on serious adverse experiences or
18 quality issues related to compounding pharmacies that
19 are distributing interstate. She stated boards are
20 obligated to submit information concerning adverse
21 experiences or quality issues related to products
22 compounded by a physician and distributed interstate.
23 She noted the boards are also obligated to provide
24 information related to the distribution interstate of
25 any amount of compounded products by a physician.

1 Dr. Madigan noted the Board is required to
2 determine the inordinate amount by either surveying
3 their licensees, review records during inspections,
4 use NABP's information-sharing network, or find other
5 mechanisms that work. She stated the MOU does not
6 require a board to input any compounding pharmacy data
7 into the information-sharing network but does allow a
8 board to meet its obligation to determine compounding
9 of an inordinate amount through the use of the
10 information-sharing network.

11 Dr. Madigan stated NABP received a grant from the
12 FDA to develop the information-sharing network. She
13 mentioned that NABP is adapting its existing e-Profile
14 Connect data management system by adding data fields.
15 She noted both boards and pharmacies will be able to
16 enter data by uploading documents, including
17 complaints and inspection forms.

18 Dr. Madigan informed the Board that it is part of
19 a three-year pilot project, and NABP will be providing
20 the FDA with analysis to see if the information-
21 sharing system provides accurate information at the
22 end of the project.

23 Dr. Madigan commented that the system will
24 automatically notify the board if it is determined
25 that an inordinate amount of compounding product is

1 being distributed interstate by a compounding
2 pharmacy, where the board can come back into the
3 system, review the data, and be able to push a button
4 for the information to be submitted to the FDA.

5 Dr. Madigan addressed data fields and compounding
6 activity. She noted data will be inserted so an
7 inordinate amount calculation can be made
8 automatically. She mentioned information will be
9 collected about the number of sterile compounded
10 products distributed interstate.

11 Dr. Madigan noted boards have 30 days to notify
12 the FDA of inordinate amounts. She stated the board
13 will be obligated to enter information into the system
14 for serious adverse drug experience or serious product
15 quality issues when the product is being distributed
16 outside the state.

17 Dr. Madigan stated the name of the complainant,
18 the name of the pharmacy, and complaint itself need to
19 be submitted no later than five business days. She
20 also stated the information regarding the assessment
21 and investigation did not need to be submitted to the
22 FDA until after the investigation was completed.

23 Dr. Madigan addressed notifying the FDA of
24 complaints about physicians when there was an adverse
25 drug experience or product quality issue distributed

1 outside the state, where the Board would be required
2 to provide information no later than five business
3 days. She also mentioned that a board has 30 days to
4 notify the FDA about a physician regarding
5 distribution outside of the state and is obligated to
6 notify the state regulator of physicians in both
7 cases.

8 Dr. Madigan addressed two pathways for collection
9 of compounding data for the calculation of the
10 inordinate amount. She mentioned the addition of data
11 fields to the pharmacy accreditation program
12 application and the Verified Pharmacy Program (VPP)
13 inspection application. She stated the pharmacy will
14 pay the regular accreditation or inspection
15 application fee with no extra charge. She noted
16 another pathway, where a pharmacy could also go into
17 its own e-Profile and submit the data into the data
18 fields.

19 Dr. Madigan reported the second pathway was up
20 and running, but the accreditation piece was not ready
21 yet and expected to be ready at the end of April.

22 Dr. Madigan informed the Board that NABP will be
23 offering pharmacies a complementary VPP inspection at
24 no cost if pharmacies submit the data, and pharmacies
25 that already submitted an application will be refunded

1 that amount.

2 Dr. Madigan addressed NABP goals, including
3 protecting the public and having an ongoing means of
4 reporting information. She mentioned the vast
5 majority of states are in the process of determining
6 whether or not to sign the MOU. Several have said
7 they will sign, and one state has signed.

8 Dr. Madigan noted that a majority of states had
9 not signed due to technical reasons, because the
10 contract did not comply with state requirements for
11 contracts. NABP will be working with the FDA to seek
12 alternatives. She reported some states already
13 collect this information and were considering
14 requiring pharmacies to submit the information to
15 NABP.

16 Dr. Madigan informed the Board of a new page on
17 NABP's website dedicated to the project with a link to
18 the MOU, FAQs, map of state MOU decisions, and slide
19 deck.

20 Mr. Ruiz commented that in the state of
21 Pennsylvania many powers are split between the Board
22 and the Department of Health. He stated the MOU
23 requires all pharmacies be surveyed but wanted to
24 verify that the survey would not be needed if the
25 Board participated in the information-sharing network.

1 Dr. Madigan confirmed that to be correct, stating
2 that the data could be utilized to comply with the MOU
3 when it comes to reporting inordinate amounts.

4 Dr. Madigan noted NABP is working with the
5 pharmacy associations to educate their members about
6 the information-sharing network and would also work
7 with boards rather than going directly to licensees.

8 Neal Watson, Senior Manager, Member Relations and
9 Government Affairs, National Association of Boards of
10 Pharmacy, mentioned that some of the other states are
11 actually considering require pharmacies that meet
12 certain thresholds to report directly to the NABP
13 information-sharing network through regulation. He
14 commented that NABP has prepared model language that
15 is ready to be put into their model act as well.

16 Mr. Ruiz requested information regarding who
17 would have access to the information uploaded into the
18 information-sharing network.

19 Dr. Madigan stated the FDA would not have access
20 and would only have information that the state
21 transmits to them through NABP's system. She noted
22 the FDA did not want access and only wanted to follow
23 the MOU, which is how it is written.

24 Mr. Watson stated NABP has an e-Profile Connect
25 system that the Board will have access to.

1 Mr. Ruiz addressed an issue with reporting of
2 complaints, where the statute in Pennsylvania makes
3 all complaints confidential. He stated the
4 information can be shared with law enforcement
5 agencies and other state licensing boards but sharing
6 with NABP does not fall into one of those categories
7 under the act.

8 Mr. Ruiz noted a final decision may be shared but
9 complaints just received are confidential and
10 questioned whether NABP would be willing to enter into
11 an MOU with the Board for that purpose.

12 Dr. Madigan noted that to be a question NABP
13 asked the FDA and was waiting on an interpretation
14 because of the way the MOU is written, where if it is
15 confidential, it is not available.

16 Mr. Ruiz also noted an issue with the five-day
17 reporting period, where it is not known if a complaint
18 relates to compounding until the investigation starts.

19 Dr. Madigan informed the Board that the FDA will
20 be holding many meetings with small groups of states
21 sometime in April, so the Board will be able to ask
22 questions and hear from other boards.

23 Mr. Michalowski questioned whether there had been
24 any discussion with the FDA regarding whether it would
25 be sufficient if a state did not require it.

1 Dr. Madigan explained that it covers states that
2 do not require submission of data. She stated NABP
3 will be contacting the pharmacy associations,
4 marketing the program, and providing the opportunity
5 to get the free inspection. She noted 30 pharmacies
6 have submitted the data, but NABP had not reached out
7 to anyone yet. She noted it was up and running
8 because that functionality was added first, but the
9 other functionalities were not ready yet. Even though
10 New Hampshire signed up, it could not submit anything
11 yet.

12 Mr. Michalowski questioned whether there was a
13 tool built into the system to alert the Board when a
14 pharmacy goes over the threshold and the FDA would
15 need to be notified.

16 Dr. Madigan explained that the system, at the end
17 of April, will be available to send the Board office a
18 notification of the addition of a pharmacy that went
19 over the threshold, where the Board can look at the
20 data and submit it to the FDA.

21 Mr. Michalowski commented that the Pennsylvania
22 Board of Pharmacy had no jurisdiction over doctors
23 regarding compounding and are overseen either by the
24 Department of Health, Board of Medicine, or Board of
25 Osteopathic Medicine. He noted that it did not sound

1 like the language in the MOU would apply to this
2 Board.

3 Dr. Madigan commented that most states do not
4 have authority over the medical professions, and the
5 FDA did not anticipate many reports regarding
6 physicians. She mentioned there may be an instance
7 where a patient might contact the Board of Pharmacy
8 with information about an adverse reaction or a
9 similar matter. That is when the Board would be
10 obligated to input that information.

11 Mr. Michalowski mentioned that Pennsylvania is an
12 umbrella state, and all of the licensing boards are
13 together. He stated the prosecution division works
14 with all 29 licensing boards and would not bring a
15 complaint submitted to the Board of Medicine or Board
16 of Osteopathic Medicine to the Board of Pharmacy.

17 Mr. Michalowski stated the Board would not see
18 any of the complaints ahead of time, only when the
19 matter was ready for adjudication or settlement.]

20

21 Introduction of Audience Members

22 [Theodore Stauffer, Executive Secretary, Bureau of
23 Professional and Occupational Affairs, provided an
24 introduction of audience members.]

25

1 Public Comment

2 [Ray Michalowski, Esquire, Senior Board Prosecution
3 Liaison, mentioned there is a lot of confusion when
4 interpreting existing waivers regarding vaccinations
5 and whether or not pharmacy technicians in
6 Pennsylvania can vaccinate. He referred to the Public
7 Readiness and Emergency Preparedness (PREP) Act. He
8 stated the Pennsylvania waivers include the ability to
9 go to certain ages, ability for pharmacists to provide
10 COVID vaccinations, and the ability for pharmacy
11 interns to vaccinate when appropriately trained.

12 Mr. Michalowski addressed the PREP Act regarding
13 pharmacy technicians, noting confusion in the
14 industry. He stated it was not the Board's ability to
15 put out a waiver but recommended having a discussion
16 and receiving input before recommending a waiver at
17 the executive level.

18 Mr. Michalowski mentioned seeing many differences
19 of opinion in the industry, noting he did not want to
20 be in the way of people being vaccinated nor did he
21 wish to allow people who should not be vaccinating to
22 vaccinate.

23 Mr. Ruiz referred to guidance issued by the U.S.
24 Department of Health & Human Services (HHS) that
25 provides a definition of a qualified pharmacy

1 technician and requirements including the 20-hour
2 Accreditation Council for Pharmacy Education (ACPE)
3 training program, be certified in cardiopulmonary
4 resuscitation (CPR), and be supervised by a
5 pharmacist.

6 Mr. Ruiz noted that authorization even preempts
7 any state and local law that prohibits or effectively
8 prohibits those who satisfy those requirements. He
9 stated Pennsylvania law does not address pharmacy
10 technicians vaccinating or give pharmacy technicians
11 the ability to vaccinate, so there is nothing to
12 waive.

13 Mr. Ruiz stressed that the Board has its own
14 definition for a qualified pharmacy technician, and it
15 requires supervision by a pharmacist who is readily
16 and immediately available to assist. He noted the
17 pharmacist would also have to comply with
18 recordkeeping rules.

19 Nicole Corbett, Pharmacy Technician, Walgreens,
20 suggested all departments know everything upfront for
21 clarification to avoid causing undue stress. She
22 mentioned working with Operation Warp Speed and legal
23 attorneys in the state.

24 Mr. Stauffer presented a question in Q&A from
25 Barbara Knightly, Executive Vice President of

1 Pharmacy, Pentec Health, noting the Pennsylvania
2 Department of Health oversees 503Bs and not 503As, so
3 why the concern if MOU is only applicable to 503A
4 pharmacies.

5 Mr. Ruiz explained that the issue comes down to
6 one of the definitions related to identifying the risk
7 to the public. He mentioned not having the authority
8 to say that the compounding drug was an immediate risk
9 to the public. He stated this matter was covered in
10 the Drug Act under the purview of the Department of
11 Health. He will be reaching out to the FDA to discuss
12 additional issues to be resolved before signing the
13 MOU.

14 Mr. Stauffer noted a follow-up comment from Ms.
15 Knightly, where many states require nonresident
16 pharmacies to be inspected by NABP'S VPP, so most of
17 the pharmacies that are dispensing interstate are
18 likely self-reporting to NABP when applying for their
19 VPP inspection requirement prior to renewals.

20 Mr. Ruiz commented that the reason NABP was
21 speaking today is to apprise all of how the
22 information-sharing network will work with the MOU and
23 the Board's responsibilities under the MOU.

24 Mr. Stauffer noted a question received from
25 Steven Zahn, Pharmacy Inspector, Bureau of Enforcement

1 and Investigation, Department of State, asking whether
2 delegating authority is needed from pharmacists to
3 technicians for administration of vaccinations.

4 Mr. Michalowski explained that the current
5 delegation regulation does not mention vaccines,
6 because it was written prior to the technician law
7 being passed.

8 Ms. Talbott commented that there would be nothing
9 prohibiting just adding language in the technician's
10 protocol.

11 Mr. Ruiz stated the protocol is to be followed by
12 the pharmacists. He noted the importance of focusing
13 on the supervision aspect, where technicians should
14 not be doing this on their own without proper
15 supervision.

16 Mr. Stauffer noted Steve Sheaffer, Pharm.D.,
17 Pennsylvania Society of Health-System Pharmacists,
18 requested information concerning student registration
19 to administer injectables. He questioned whether a P2
20 student that registers and their training is beyond 2
21 years when they become a licensed pharmacist would
22 have to repeat their immunization training. Ms.
23 Talbott explained that a P2 would have to repeat their
24 training because of the current regulation. She
25 mentioned the training was extended to 3 years in the

1 proposed regulations, but the regulations are not
2 finalized.

3 Mr. Stauffer noted a follow-up comment from Dr.
4 Sheaffer, where the protocol for a particular
5 technician must include immunizing.

6 Mr. Michalowski stated the Board could define a
7 best practice, and the Board does not enforce best
8 practices but can endorse them.]

9

10 [K. Kalonji Johnson, Commissioner, Bureau of
11 Professional and Occupational Affairs, entered the
12 meeting at 11:48 a.m.]

13

14 Report of Commissioner

15 [K. Kalonji Johnson, Commissioner, Bureau of
16 Professional and Occupational Affairs, informed the
17 Board that the department will continue to work with
18 the Department of Health (DOH) to ensure they are
19 supporting their efforts and making sure the Board's
20 concerns are adequately voiced and communicated while
21 moving through the new phase of various regulatory
22 suspensions and related language.

23 Ms. Talbott questioned whether retired
24 individuals with an active license and who may want to
25 volunteer their services at medical points of

1 dispensing (POD) would be able to do so. Commissioner
2 Johnson explained that there would need to be a
3 discussion with policy to develop steps for that
4 process. He stated the department will work with the
5 Department of Health to best message those efforts and
6 integrate it into the existing temporary licenses,
7 emergency reactivations, and existing regulatory
8 suspensions to provide the correct set of
9 instruction.]

10 ***

11 Adjournment

12 CHAIRPERSON HART:

13 Motion to adjourn?

14 MS. TALBOTT:

15 I'll make that motion.

16 MR. FRANKIL:

17 Second.

18 CHAIRPERSON HART:

19 All in favor, aye? Opposed.

20 [The motion carried unanimously.]

21 ***

22 [There being no further business, the State Board of
23 Pharmacy Meeting adjourned at 11:52 a.m.]

24 ***

25

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

CERTIFICATE

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



Derek Richmond,
Minute Clerk
Sargent's Court Reporting
Service, Inc.

STATE BOARD OF PHARMACY
REFERENCE INDEX

March 17, 2021

	TIME	AGENDA
1		
2		
3		
4		
5		
6		
7		
8		
9	9:00	Executive Session
10		
11	10:30	Return to Open Session
12		
13	10:33	Official Call to Order
14		
15	10:33	Introduction of Board Members and Staff
16		
17	10:36	Approval of Minutes
18		
19	10:37	Report of Prosecutorial Division
20		
21	10:39	Report of Board Counsel
22		
23	10:41	Report of Board Chairperson
24		
25	10:43	Report of Executive Secretary
26		
27	10:45	New Business
28		
29	10:46	Motions
30		
31	10:55	Appointment - FDA's MOU and NABP's
32		Compounding Pharmacy Information-
33		Sharing Project
34		
35	11:30	Introduction of Audience Members
36		
37	11:35	Public Comment
38		
39	11:48	Report of Commissioner
40		
41	11:52	Adjournment
42		
43		
44		
45		
46		
47		
48		
49		
50		