



# NEVADA STATE BOARD OF PHARMACY

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## MINUTES

January 13, 2021

## BOARD MEETING

Pursuant to Governor Steve Sisolak's Emergency Directive 006, there will be no physical location for this meeting. The meeting can be listened to or viewed live over Zoom.

Via Videoconference at Zoom:  
<https://zoom.us/j/5886256671>

or

Via Teleconference at 1 (669) 900-6833  
Meeting ID: 588 625 6671

### Board Members Present:

Helen Park	Jade Jacobo	Krystal Freitas	Gener Tejero
Wayne Mitchell	Rolf Zakariassen	Richard Tomasso	

### Board Staff Present:

Dave Wuest	Yenh Long	Shirley Hunting	Courtney Lee
Brett Kandt	Joe Dodge	Dena McClish	Kristopher Mangosing
Sophia Long	Ken Scheuber	Shannon Reichman	

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

Dave Wuest stated that this Board Meeting is being held over Zoom and is in compliance with the Governor's directive and Open Meeting Laws for Nevada.

### 1. Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. All Board members were present and a quorum was established.

2. Public Comment January 13, 2021, 9:14 AM

There was no Public Comment.

3. Approval of the December 2, 2020, Meeting Minutes

Board Action:

Motion: Wayne Mitchell moved to approve the December 2, 2020 minutes

Second: Jade Jacobo

Action: Passed unanimously.

4. 4.1 Applications for Out-of-State Pharmacy License – Non-appearance

- A. C3 Pharmacy – St. George, UT
- B. Cary Rx Incorporated – Washington DC
- C. CoAssist Pharmacy, LLC – Orlando, FL
- D. Continued Care LTC Pharmacy Idaho LLC – Boise, ID
- E. Eagle Pharmacy – Lakeland, FL
- F. Health Haven Pharmacy – Nashua, NH
- G. MedWiseRx – Phoenix, AZ

4.2 Application for Out-of-State Compounding Pharmacy License – Non-appearance

- H. Children’s Hospital Los Angeles Specialty Pharmacy – Los Angeles, CA
- I. Nationwide Compounding Rx, LLC – Scottsdale, AZ

4.3 Applications for Out-of-State Medical, Devices, Equipment and Gases License – Non-appearance

- J. Embody, Inc. – Norfolk, VA
- K. First Nation Group, LLC – Detroit, MI
- L. First Nation Group, LLC – Ft. Myers, FL.
- M. Mohawk DME – Akwesasne, NY

4.4 Applications for Out-of-State Wholesaler License – Non-appearance

**Background Check Not Required by Law.**

4.4.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))

4.4.2 Manufacturer (NAC 639.593(7)(d))

- N. Aurinia Pharma U.S., Inc. – Rockville, MD
- O. Metuchen Pharmaceuticals, LLC – Manalapan Township, NJ
- P. Myovant Sciences, Inc. – Brisbane, CA
- Q. Solco Healthcare U.S. LLC – Somerset, NJ
- R. Urovant Sciences, Inc. – Irvine, CA
- S. Xiros, Inc. – Mansfield, MA

4.4.3 Publicly Traded (NAC 639.593(7)(a))

- T. McKesson Medical-Surgical Inc.

4.4.4 VAWD-Accredited (NAC 639.593(7)(c))  
None

4.5.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

- U. Precision Dose, Inc. – South Beloit, IL

4.4.5 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

- V. Harmony Biosciences, LLC – Plymouth Meeting, PA
- W. Portola Pharmaceuticals, LLC – South San Francisco, CA
- X. Zyla Life Sciences US Inc. – Wayne, PA

4.4.6 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))  
None

4.4.7 **Background checks completed in compliance with NRS 639.500. No Disqualifying Events.**

- Y. Astor Pharmaceuticals LLC – Holtsville, NY
- Z. Oakrum Pharma, LLC – St. Louis, MO
- AA. Premier Pharmaceuticals LLC – Boise, ID
- BB. Redwood Distribution – El Paso, TX
- CC. Sobi, Inc. – Waltham, MA
- DD. US VET, INC. – Liverpool, NY

Krystal Freitas expressed concern that the Facility Manager for Consent Agenda Item 4BB may not meet the requirements and asked that it be pulled from the Consent Agenda.

**Board Action:**

**Motion:** Jade Jacobo moved to approve the Consent Agenda with the exception of Item 4BB.

**Second:** Krystal Freitas

Action: Passed unanimously.

5. Disciplinary hearings pursuant to NRS 639.247.

A. Kiarash L. Mirkia, MD

(19-090-CS-S)

Kiarash Mirkia appeared and was sworn by President Park prior to answering questions or offering testimony.

Melanie Thomas was present as counsel representing Dr. Mirkia.

Brett Kandt, General Counsel, summarized the facts of the case and presented a Stipulation and Order for the Board's consideration.

The Stipulation and Order shall be considered public reprimand. Controlled substance registration number CS15197 for Dr. Mirkia shall remain in inactive status until proof that his License Number 12548 to practice medicine from the Nevada State Board of Medical Examiners is active and in good standing. Dr. Mirkia must appear before the Board and petition for reinstatement of his Controlled Substance Registration.

Dr. Mirkia shall pay a fine of \$1,500 to the state of Nevada and shall pay \$1,000 to the Board for recoverable attorney fees and costs.

Ms. Thomas had no objections to the Stipulation and Order presented and Mr. Kandt's summary of the case.

#### Board Action

Motion: Wayne Mitchell moved to accept the Stipulation and Order as presented.

Second: Jade Jacobo

Action: Passed unanimously.

B. John Phoenix, APRN

(19-143-CS-S)

John Phoenix appeared and was sworn by President Park prior to answering questions or offering testimony.

Tracy Singh was present as counsel representing Mr. Phoenix.

Mr. Kandt summarized the facts of the case and presented a Stipulation and Order for the Board's consideration.

The Stipulation and Order shall serve as a public reprimand. Mr. Phoenix shall pay \$950 to the Board for recoverable attorney fees and costs.

Ms. Singh had no objection to the Stipulation and Order presented and Mr. Kandt's summary of the case.

Board Action:

Motion: Wayne Mitchell moved to approve the Stipulation and Order as presented.

Second: Jade Jacobo

Action: Passed unanimously.

C. Erika Smith, DDS

(19-123-CS-S)

Dr. Smith was not present.

Mr. Kandt called Shirley Hunting, Board Coordinator, as a witness.

Ms. Hunting appeared and was sworn by President Park prior to answering questions or offering testimony.

Ms. Hunting testified that she sent Dr. Smith the Notice of Intended Action and Accusation by certified mail. Ms. Hunting reviewed documentation showing that Dr. Smith was properly served at her address of record.

Mr. Kandt asked that Exhibit A be admitted into the record.

President Park admitted Exhibit A into the record.

Mr. Kandt presented Exhibit A to the Board. Exhibit A was documentation that Board Staff properly noticed Dr. Smith by certified mail to her address of record.

Ken Scheuber, Board Investigator, appeared and was sworn by President Park prior to answering questions or offering testimony.

Mr. Scheuber answered Mr. Kandt's questions regarding a phone conversation Mr. Scheuber had regarding serving Dr. Smith her Notice of Intended Action and Accusation.

Mr. Kandt stated that the Notice of Intended Action and Accusation were also emailed to Dr. Smith's email address of record.

Mr. Kandt stated that Board Staff properly noticed Dr. Smith and asked that the Board move to find that the respondent has been properly noticed in compliance with NRS 639.242.

Board Action:

Motion: Jade Jacobo moved to find that respondent Dr. Erika Smith was properly noticed in compliance with NRS 639.242

Second: Richard Tomasso

Action: Passed unanimously.

Mr. Kandt asked the Board to find that they have jurisdiction over this matter as stated in paragraph one of the Notice of Intended Action and Accusation,

Board Action:

Motion: Jade Jacobo moved that the Board has jurisdiction over this matter.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Kandt asked that the Board make Findings of Fact consistent with paragraphs two and three of the Accusation, that Erika Smith's license to practice as a dentist was revoked by the Nevada State Board of Dental Examiners. She was later served with Notice of Intended Action and Accusation by the Nevada Board of Pharmacy, and that the revocation of her license to practice dentistry operated as the immediate suspension of her registration with the Board.

Board Action:

Motion: Jade Jacobo moved to make Findings of Fact consistent with paragraphs two and three of the Accusation, that Erika Smith's license to practice as a dentist was revoked by the Nevada State Board of Dental Examiners and that she was served with Notice of Intended Action and Accusation by the Nevada Board of Pharmacy. The revocation of her license to practice dentistry operated as the immediate suspension of her registration with the Board.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Kandt asked that the Board move to make Conclusions of Law consistent with paragraphs four through nine of the Accusation, and the Causes of Action alleged therein.

Board Action:

Motion: Jade Jacobo moved to make Conclusions of Law consistent with paragraphs four through nine of the Accusation, and the Causes of Action alleged therein

Second: Richard Tomasso

Action: Passed unanimously.

Mr. Kandt asked that the Board revoke Erika Smith's Controlled Substance Registration number CS17603, effective immediately, and be effective for a minimum of one year before she may petition for reinstatement.

Board Action:

Motion: Jade Jacobo moved to revoke Erika Smith's Controlled Substance Registration number CS17603, effective immediately, and be effective for a minimum of one year before she may petition for reinstatement.

Second: Rolf Zakariassen

Action: Passed unanimously.

D. Derek Braddix, APRN

(17-125-CS-A-N)

Derek Braddix appeared and was sworn by President Park prior to answering questions or offering testimony.

Mr. Kandt summarized the facts of the case and stated that Mr. Braddix provided additional documents, and requested that they be admitted into the record.

President Park admitted the documents into the record.

Mr. Braddix stated that his APRN license was not renewed in November 2020. As his license is expired, he asked that no action be taken against his license.

Mr. Kandt provided insight into the legalities surrounding Mr. Braddix's DEA Surrender for Cause.

Mr. Braddix answered questions regarding the investigation of his DEA registration.

Mr. Kandt asked the Board to move that they have jurisdiction over this matter as alleged in paragraph one of the Accusation.

Board Action:

Motion: Wayne Mitchell moved that the Board has jurisdiction over this matter as stated in Paragraph one of the Accusation.

Second: Jade Jacobo

Action: Passed unanimously.

Mr. Kandt asked that the Board make Findings of Fact consistent with paragraphs two, three and four of the Accusation, and an additional Finding of Fact that the respondent's license with the Nevada State Board of Nursing expired on or about November 8, 2020.

Board Action:

Motion: Wayne Mitchell moved to make Finding of Facts consistent with paragraphs two, three, and four of the Accusation, and an additional Finding of Fact that Mr. Braddix's license with the Nevada State Board of Nursing expired on or about November 8, 2020.

Second: Jade Jacobo

Action: Passed unanimously.

Mr. Kandt asked the Board to make Conclusions of Law consistent with paragraphs five and six of the Accusation, and an additional Conclusion of Law that the respondent does not qualify to hold a Controlled Substance Registration because he is not licensed with the Nevada State Board of Nursing.

Board Action:

Motion: Wayne Mitchell moved to make Conclusions of Law consistent with paragraphs five and six of the Accusation, and an additional Conclusion of Law that the respondent does not qualify to hold a Controlled Substance Registration because he is not licensed with the Nevada State Board of Nursing

Second: Rolf Zakariassen

Action: Passed unanimously.

Mr. Kandt asked that the Board revoke the respondent's certificate of registration number CS25303 effective immediately and that the respondent may not petition for reinstatement of licensure with the Board for a minimum of one year.

Board Action:

Motion: Wayne Mitchell moved to revoke the respondent's certificate of registration number CS25303 effective immediately and that the respondent may not petition for reinstatement of licensure with the Board for a minimum of one year.



Second: Krystal Freitas

Action: Passed unanimously.

E. Jesse Mai, FNP-C

(19-054-CS-S)

Jesse Mai was not present.

Mr. Kandt provided background that Jesse Mai surrendered his DEA Certificate of Registration Number MR2801288 for cause and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

Mr. Kandt called Ms. Hunting as a witness.

Ms. Hunting testified that she sent Dr. Mai the Notice of Intended Action and Accusation by certified mail. Ms. Hunting reviewed documentation showing that Dr. Mai was properly served at his address of record.

Mr. Kandt asked that Exhibit A be admitted into the record.

President Park admitted Exhibit A into the record.

Mr. Kandt presented Exhibit A to the Board. Exhibit A was documentation that Board Staff properly noticed Dr. Mai by certified mail to her address of record.

Mr. Kandt asked that Dr. Mai's surrender for cause of his DEA Registration be admitted into the record.

President Park admitted Dr. Mai's surrender for cause of his DEA Registration into the record.

Mr. Kandt asked that the Board find that Dr. Mai was given sufficient legal notice of this hearing

Board Action:

Motion: Krystal Freitas moved to find that Dr. Mai was given sufficient legal notice of this hearing.

Second: Jade Jacobo

Action: Passed unanimously.

Mr. Kandt asked that the Board find that they have jurisdiction over this matter consistent with paragraph one of the Accusation.

Board Action:

Motion: Krystal Freitas moved to find that the Board has jurisdiction over this matter consistent with paragraph one of the Accusation.

Second: Jade Jacobo

Action: Passed unanimously.

Mr. Kandt asked that the Board make Findings of Fact consistent with paragraphs two, three and four of the Accusation.

Board Action:

Motion: Krystal Freitas moved to make Findings of Fact consistent with paragraphs two, three, and four of the Accusation.

Second: Jade Jacobo

Action: Passed unanimously.

Mr. Kandt asked that the Board move to make Conclusions of Law consistent with paragraphs five and six of the Accusation.

Board Action:

Motion: Krystal Freitas moved to make Conclusions of Law consistent with paragraphs five and six of the Accusation.

Second: Jade Jacobo

Action: Passed unanimously.

Mr. Kandt asked that the Board revoke Dr. Mai's Certificate of Registration Number CS20701 effectively immediately and that Dr. Mai may not petition for reinstatement of his Controlled Substance Registration for one year.

Board Action:

Motion: Krystal Freitas moved to revoke Certificate of Registration Number CS20701 for Dr. Mai effective immediately, and that Dr. Mai may not petition for reinstatement of his license for one year.

Second: Jade Jacobo

Action: Passed unanimously.

F. Dhaval Shah, MD

(20-222-CS-S)

Johnathon Fayeghi, legal counsel for Dhaval Shah was present.

Dhaval Shah appeared and was sworn by President Park prior to answering questions or offering testimony.

Mr. Kandt provided background information and presented a Stipulation and Order for the Board's consideration. Dr. Shah's Certificate of Registration Number CS15290 and PD00165 shall be revoked and the respondent may not petition for reinstatement for a minimum of one year.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order as presented.

Second: Wayne Mitchell

Action: Passed unanimously.

G. Richard Washinsky, MD

(19-232-CS-S)

Richard Washinsky, MD, appeared and was sworn by President Park prior to answering questions or offering testimony.

Kevin Murphy was present as legal counsel representing Dr. Washinsky.

Courtney Lee, General Counsel, provided background and presented a Stipulation and Order for the Board's consideration. Dr. Washinsky's Certificate of Registration Number CS06491 be revoked, the revocation stayed, and Dr. Washinsky placed on probation for two years effective immediately. This Stipulation and Order shall serve as a public reprimand. Dr. Washinsky shall pay a fine of five thousand dollars, and shall pay two thousand dollars to the Board for recoverable attorney fees and costs. Dr. Washinsky shall comply with all federal and state laws. Upon successful completion of probation, Dr. Washinsky's Certificate of Registration Number CS06491 shall be fully restored, conditioned upon good standing with the Nevada Medical Board and DEA.

Kevin Murphy stated that there are no objections to the Stipulation and Order and clarified that Dr. Washinsky did not intentionally violate Nevada Law. The Nevada Medical Board has fined Dr. Washinsky seven thousand five hundred dollars.

Board Action:

Motion: Jade Jacobo moved to accept the Stipulation and Order as presented.

Second: Krystal Freitas

Aye: Jacobo, Freitas, Tejero, Park

Nay: Mitchell, Zakariassen, Tomasso

Action: Motion carries.

6. Application for Ambulatory Surgery Center License. – Appearance. **(FOR POSSIBLE ACTION)**

A. Affordable Excellence Surgery Center – Las Vegas, NV

This Agenda Item was heard in conjunction with Items 6B and 6C.

Mary Grear, managing pharmacist, and Jeremy Lipshutz, Owner, were present.

Mr. Lipshutz and Ms. Grear appeared and were sworn by President Park prior to answering questions or offering testimony.

Dave Wuest stated that these applications were on the consent agenda from a previous Board meeting. Mr. Lipshutz was asked to appear to provide more information on a pending litigation he disclosed on the applications.

Mr. Lipshutz described the circumstances regarding his pending litigation. He stated that the case was still pending, but explained that the case was regarding billing issues and there was no patient harm involved in the case.

After discussion, President Park offered Mr. Lipshutz and Ms. Grear the option to table this matter until Mr. Lipshutz's pending case is resolved.

President Park tabled the applications for Affordable Excellence Surgery Center, First Specialty Surgery Center and Ultimate Specialty Surgery Center at Mr. Lipshutz request.

B. First Specialty Surgery Center – Las Vegas, NV

This Item was heard in conjunction with Agenda Item 6A.

C. Ultimate Specialty Surgery Center – Las Vegas, NV

This Item was heard in conjunction with Agenda Item 6A.

7. Application for Nevada Pharmacy License – Appearance

Plus One Pharmacy, LLC – Las Vegas, NV

Courtney Lee, General Counsel, provided background information and stated that Plus One Pharmacy appeared at a previous meeting. The matter was tabled due to the Board's concerns regarding the managing pharmacist's experience.

Anisha Patel, Owner, and Christy Nguyen, managing pharmacist, appeared and were sworn by President Park prior to answering questions or offering testimony.

Ms. Nguyen answered the Board's questions regarding her experience as a managing pharmacist.

Joe Dodge stated that Ms. Nguyen worked at All City Pharmacy II. He explained that All City Pharmacy II had a fire and has been closed permanently. Ms. Nguyen worked at All City Pharmacy II and was not the last pharmacist in charge there.

After discussion, the Board expressed concern regarding Ms. Nguyen's lack of experience as a managing pharmacist.

President Park offered Ms. Patel the option to table Plus One Pharmacy, LLC's Application.

President Park tabled Plus One Pharmacy, LLC's application at Ms. Patel's request.

## 8. Applications for Nevada Compounding Pharmacy License – Appearance

### A. Monicos Pharmacy LLC – Las Vegas, NV

President Park disclosed that Karen Chan was a former student, but she stated that she is able to participate fairly and without bias in this matter.

Krystal Freitas disclosed a previous employment relationship with Karen Chan, but stated that she is able to participate fairly and without bias.

Ronak Desai, managing pharmacist, and Tamer Usef, Owner, appeared and were sworn by President Park prior to answering questions or offering testimony.

Joe Dodge questioned Ms. Desai about non-sterile compounding procedures, types of compounded medications, her experience with non-sterile compounding, and beyond use date of compounded medications.

Mr. Usef disclosed that while he was in college, he was arrested for possessing a fake ID and for making fake ID's. A few months ago, he was arrested for driving under the influence. That charge is still pending.

Mr. Usef and Ms. Desai answered questions to the Board's satisfaction.

### Board Action:

Motion: Richard Tomasso moved to approve the application for Monicos Pharmacy, LLC.

Second: Jade Jacobo

Action: Passed unanimously.

B. Pahrump Care Pharmacy – Las Vegas, NV

Waseem Sarwar, managing pharmacist, appeared and was sworn by President Park prior to answering questions or offering testimony.

Joe Dodge questioned Mr. Sarwar regarding his pharmacy experience with non-sterile compounding.

Mr. Sarwar answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the application for Pahrump Care Pharmacy.

Second: Richard Tomasso

Action: Passed unanimously.

9. Applications for Out-of-State Compounding Pharmacy License

A. Archway Apothecary – Covington, LA

E. Raymond Wilkes Jr, managing pharmacist, and Matthew Hardey, owner, appeared and were sworn by President Park prior to answering questions or offering testimony.

Joe Dodge questioned Mr. Wilkes about his work history, experience with sterile and non-sterile compounded medications, beyond use dates for compounded medications, sterilization processes and product testing.

Mr. Wilkes and Mr. Hardey answered questions to the Board's satisfaction.

Board Action:

Motion: Richard Tomasso moved to approve the Out of State Pharmacy License application for Archway Apothecary.

Second: Jade Jacobo

Action: Passed unanimously.

## B. Pope Shenouda LLC – Holiday, FL

George Hanna, managing pharmacist, and Mina Shenouda, Intern, appeared and were sworn by President Park prior to answering questions or offering testimony.

Dave Wuest provided background that Pope Shenouda had previously appeared but tabled their application to have the compounding pharmacist appear and answer the Board's questions.

Mr. Hanna stated that Pope Shenouda is appearing to answer questions regarding the competency of the managing pharmacist and the compounding intern.

Joe Dodge questioned Mr. Hanna about the compounding intern and his responsibilities. Mr. Hanna stated that Mr. Shenouda was the intern and is now the pharmacist.

After Board discussion, it was discovered that Mr. Shenouda is not yet licensed as a pharmacist.

The Board expressed concern regarding Mr. Hanna's knowledge regarding sterile compounding and that Mr. Hanna incorrectly represented Mr. Shenouda as a licensed pharmacist.

### Board Action:

Motion            President Park moved to deny the Nevada Compounding License for Pope Shenouda.

Second:        Rolf Zakariassen

Action:         Passed unanimously.

## 10. Application for Nevada Medical, Devices, Equipment and Gases License

### A. ActivStyle, Inc. – Reno, NV

Courtney Lee, General Counsel, provided background that ActivStyle previously appeared but the application was tabled. They are reappearing for reconsideration of approval for their MDEG application.

Rolf Zakariassen disclosed that he was employed at the CVS store where Ms. Bussard listed that she was employed. He stated that he is able to participate in this matter fairly and without bias.

Mr. Zakariassen stated that he was unfamiliar with Ms. Bussard's employment history at CVS.

Amanda Bussard, MDEG Administrator, and Shontaia Dixon, Compliance Officer, appeared and were sworn by President Park prior to answering questions or offering testimony.

Ms. Dixon stated that the MDEG Administrator has been given additional training. Ms. Bussard discussed her work experience related to being the MDEG administrator.

The Board discussed concern about the legitimacy of the hours listed by Ms. Bussard to qualify her to be the MDEG Administrator.

President Park offered Ms. Dixon and Ms. Bussard the option to table ActivSyle, Inc.'s application.

President Park tabled ActivStyle, Inc.'s application at Ms. Dixon's request.

#### B. First Care Medical Supply LLC – Las Vegas, NV

Knarik Avagyan, Director, and Sarah Katrzhyan, MDEG Administrator, appeared and were sworn by President Park prior to answering questions or offering testimony.

Dave Wuest provided background information and stated that First Care Medical Supply LLC had previously appeared and had requested their application be tabled.

The Board questioned Ms. Katrzhyan about her work experience. Ms. Katrzhyan did not answer questions to the Board's satisfaction and did not meet the requirements to be the MDEG Administrator.

President Park offered Ms. Avagyan the option to table First Care Medical Supply LLC's application.

President Park tabled First Care Medical Supply LLC's application at Ms. Avagyan's request.

#### C. Nevada Limb & Brace, LLC – Henderson, NV

Roger Beihl, MDEG Administrator, and Vanis Gardea, director, appeared and were sworn by President Park prior to answering questions or offering testimony.

Richard Tomasso was absent for the beginning of this Item but a quorum was still present.

Courtney Lee, General Counsel, provided background that this is a new MDEG license and administrator application. Nevada Limb & Brace, LLC appeared at a previous meeting where the application was tabled. They are appearing for consideration of the MDEG License in the state of Nevada.

Richard Tomasso returned and a quorum was still present.



Mr. Beihl answered questions to the Board's satisfaction regarding his work experience and the products and services provided by Nevada Limb & Brace, LLC.

Board Action:

Motion: Jade Jacobo moved to approve the In-State Application for MDEG facility Nevada Limb & Brace, LLC.

Second: Krystal Freitas

Action: Passed unanimously.

D. VieMed – Reno, NV

Brett Stoute, Chief Operations Officer, and Brandylin Trimble, MDEG Administrator, appeared and were sworn by President Park prior to answering questions or offering testimony.

Courtney Lee, General Counsel, provided background information that VieMed had appeared at a previous Board Meeting, but the application was tabled at Mr. Stoute's request.

Ms. Trimble answered questions regarding her work experience related to being the MDEG Administrator.

After discussion, the Board expressed concern about potential unlicensed practice at VieMed's Reno location.

President Park offered Mr. Stoute the option to table VieMed's application.

President Park tabled VieMed's application at Mr. Stoute's request.

11. Application for Out-of-State Outsourcing Facility

Sincerus Florida, LLC – Pompano Beach, FL

Jenny Liu, pharmacist in charge, Jonathan Fenster, Chief Operating Officer, and Abul Bhuiyan, Vice President of Scientific Affairs, and Ondrej Staviscak-Diaz, Sincerus General Counsel, appeared and were sworn by President Park prior to answering questions or offering testimony.

Joe Dodge, Board Inspector, appeared and was sworn by President Park prior to answering questions or offering testimony.

Bill Stilling was present as legal counsel for Sincerus Florida LLC.

Gener Tejero disclosed a professional relationship with Mr. Stilling but stated that he is able to participate fairly and without bias.

Dave Wuest, Executive Secretary, provided background information and stated that Sincerus Florida LLC had previously appeared and requested to table their application at that time.

Mr. Dodge questioned Sincerus Florida LLC about the non-sterile compounded medications that will be shipped to Nevada, policies and procedures, and past FDA inspections.

Sincerus Florida LLC answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the Out of State Outsourcing Facility license application for Sincerus Florida LLC.

Second: Helen Park

Aye: Mitchell, Jacobo, Park, Freitas, Tomasso, Zakariassen

Nay: Tejero

Action Motion carries.

12. Discussion and Possible Action to Request an Attorney General's Opinion pursuant to NRS 228.150 on whether Nevada law authorizes the Board to license and regulate wholesalers of veterinary biological products and/or animal vaccine products in Nevada; and if so, whether such authority is preempted by federal law.

Courtney Lee, General Counsel, provided background that the Board is asking for approval to seek an Attorney General's Opinion on the ability of the Board to regulate wholesalers of veterinary biological products and/or animal vaccine products in Nevada.

Ms. Lee discussed definitions of Nevada Pharmacy Law and the implications of regulating the wholesalers of veterinary biological products and/or animal vaccine products in Nevada.

Board Action:

Motion: Jade Jacobo moved to grant Board Staff the authority to seek the Attorney General's Opinion on the ability of the Board to regulate the wholesalers of veterinary biological products and/or animal vaccine products in Nevada; and if so, whether such authority is preempted by federal law

Second: Richard Tomasso

Action: Passed unanimously.

Mr. Kandt clarified for the record that there is a distinction between regulating biological products and regulation of a party transporting that product into the State of Nevada.

President Park opened the floor to Public Comment.

Trevor Newhouse, attorney, stated that there is a conflict between regulatory agencies and agrees that an opinion from the Attorney General would be of value.

President Park closed Public Comment

13. Discussion and possible action on approval of Asher College as a program of training for pharmaceutical technicians pursuant to NAC 639.256

Kathryn Johnson, Bill Zavatchon, Ann Buzak, were present.

Mr. Wuest provided background information and discussed the requirements for pharmaceutical technician training programs.

Ms. Johnson answered questions regarding Asher College's training curriculum and policies and procedures.

Ms. Johnson stated that Asher College is still in candidate status for accreditation. She explained the policies for drug testing students.

After discussion, President Park offered Ms. Johnson the option to table Asher College's request.

President Park tabled this matter at Ms. Johnson request.

14. General Counsel Report. Note: The Board may exclude the public for a report on potential or existing litigation pursuant to NRS 241.015(3)(b)(2).

Brett Kandt, General Counsel, discussed the results of litigation involving the Board.

15. Executive Secretary Report:

A. Financial Report

Mr. Wuest presented the financials to the Board's satisfaction.

B. Issuance of Temporary Licenses and Registrations

Mr. Wuest stated that there were three additional temporary licenses issued to Pharmacy Interns to assist in COVID-19 vaccinations.

- C. Change of Address Business List
- D. Meetings with Other Health Care Regulatory Boards
- E. COVID-19 Response

President Park thanked Board Staff for their efforts in assisting with vaccinations and keeping the daily operations of the Board in effect.

- F. Licensing Software Update
- G. Licensing Activities Report
- H. PMP Integration

16. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2)

**Amendment of Nevada Administrative Code (NAC) 639.** The proposed amendment revises provisions relating to the operation of pharmacies in recovery centers and surgical centers for ambulatory patients. (LCB File No. R085-20)

Brett Kandt, General Counsel, summarized the proposed amendments

Mr. Kandt recommended one revision to the proposed language to remove duplicative fees.

President Park opened Public Comment.

Scott Weiss, President for The Healthcare Consulting Group LLC, expressed support of the proposed language

Board Action:

Motion: Jade Jacobo moved to adopt the proposed regulation LCB File No. R085-20 with the recommended amendment as presented by Board Staff.

Action: Krystal Freitas

Second: Passed unanimously.

17. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2)

- A. **Amendment of Nevada Administrative Code (NAC) 639.220 Schedule of fees; penalty for late renewal; exemptions from certain fees.** The proposed amendment to NAC 639.220 will provide medical interns and residents reduced fees to prescribe or possess controlled substances and to biennially renew such authorization.

Courtney Lee, General Counsel, provided background and stated that this proposed amendment to NAC 639.220 will provide medical interns and residents reduced fees to prescribe or possess controlled substances and to biennially renew such authorization.

President Park opened the floor to Public Comment.

There was no Public Comment.

Board Action:

Motion: Jade Jacobo moved to submit the proposed regulation to LCB and move forward to Public Hearing.

Second: Krystal Freitas

Action: Passed unanimously.

- B. **Amendment of Nevada Administrative Code (NAC) 639.742, 639.743, 639.744. and 639.745: Dispensing Practitioners.** The proposed amendments will modify the supervision of dispensing technician by dispensing practitioners. These amendments will authorize dispensing practitioners in group practices to share an inventory of certain medications and centralize activities. The proposed amendments will increase the fees for the application for an initial registration, and the biennial renewal of a registration, as a registered dispensing technician.

David Wuest, Executive Secretary, provided background information.

Brett Kandt, General Counsel, read the proposed language into the record.

President Park opened the Public Comment.

Rupesh Parikh, Oncologist and President for Comprehensive Cancer Centers of Nevada, expressed his support for this proposed amendment along with some concerns.

Dr. Brian Vaicuna, Medical Oncologist for Comprehensive Cancer Centers of Nevada, expressed support of this proposed amendment.

Helen O'Hallan, patient of Dr. Parikh, provided background information of her cancer history. Ms. O'Hallan expressed support of the proposed amendment due to convenience and trust in her physicians.

Ed Cowell, patient of Dr. Vaicuna, provided background information of his cancer history. Mr. Cowell expresses support of the proposed amendment due to convenience.

Sue Cowell, wife of patient, providee her background from a caregiver perspective of a cancer patient. Mrs. Cowell expressed support of the proposed amendment.

Peyton Barcel, granddaughter of a patient, provided background of her grandfather's cancer history. Ms. Barcel expressed support of this proposed amendment to help improve the quality of life for a cancer patient.

Lindsey Harmon, Executive Director for Planned Parenthood Nevada, expressed her support for this proposed amendment.

Liz MacMenamin, VP of Government Affairs for the Retail Association of Nevada, expressed opposition to the proposed language and described her concerns regarding the proposed amendment.

Wes Falconer, CEO of Cancer Care Specialist in Reno, provided background information on cancer patients and the oral dispensing medicine program. Mr. Falconer expressed support of this proposed amendment.

Jon Bilstein, Executive Director for Comprehensive Cancer Centers of Nevada, thanked the Board for allowing public comment from the physicians, patients, and caregivers and expressed support of the proposed language.

Jaron Hildebrand, Executive Director of the Nevada State Medical Association, expressed support for the proposed amendment to help improve patient care.

Rupesh Parikh wanted to address comments made by Ms. MacMenamin earlier regarding cost. Dr. Parikh stated that they are trying to save cost not add to cost to the patient. Dr. Parikh further clarified, dispensing of drugs, and cost.

Ms. MacMenamin expressed her concern further regarding practitioners dispensing drugs

President Park closed public comment.

Board discussion ensued regarding the clarifying the proposed amendment, dispensing cost, and the process of the dispensing medication.

Board Action:

Motion: Richard Tomasso moved to forward the proposed regulation to LCB and move forward to Public Hearing.

Second: Gener Tejero

Aye: Tejero, Mitchell, Park, Freitas, Tomasso, Zakariassen

Nay: Jacobo

Action: Motion carries.

- C. **Amendment of Nevada Administrative Code (NAC) 639** The proposed amendments will add a new section providing that drugs compounded by a pharmacy, dispensing practitioner, or outsourcing facility cannot be dispensed, resold, supplied, or furnished by any entity other than the licensed entity that compounded the drug. Outsourcing facilities must have procedures to prohibit the dispensing of their compounded products by other entities. Drugs compounded by an outsourcing facility may be administered pursuant to an order of a practitioner.

Mr. Wuest provided background information.

Mr. Dodge read the proposed amendment into the record.

President Park opened the floor to Public Comment.

Ondrej Staviscak-Diaz, Sincerus Outsourcing, expressed that he is not in support of the proposed amendments.

Aaron Lopez, representative from Political Capitol representing 503A and 503B facilities, appeared and expressed concern with the proposed amendments limiting patient access to the medications provided by the Outsourcing facilities.

Lee Rosebush, chairman of the 503B Trade Association, appeared and expressed opposition to the proposed language. Mr. Rosebush asked the Board not to approve the proposed language and stated that the proposed language could negatively effect Outsourcing facilities.

Gu Quadja, Nubrador Rx, appeared and expressed opposition to the proposed language. Ms. Quadja stated that the proposed language would create hardships for providers who are trying to get medication compounded by the outsourcing facilities.

Robert Nickell, compounding pharmacist, expressed that there are differences between 503A and 503B facilities and with the proposed amendments, there are logistical implications. Mr. Nickell asked the Board to not accept the proposed regulation.

Jay McEniry, Senior Vice President for legal and governmental affairs for Fagron North America in the division of regulatory affairs, appeared expressed opposition to the proposed language and asked the Board to not proceed with the proposed amendments.

The Board discussion ensued regarding the proposed language and if there was guidance from the FDA regarding regulating outsourcing facilities.

President Park closed Public Comment.

Board Action:

Motion: Jade Jacobo moved to approve the proposed regulations and move the language to LCB and move on to Public Hearing.

Second: Wayne Mitchell

Action: Passed unanimously.

18. Date and Location of Next Scheduled Board Meeting:

March 3-4, 2021 – Reno, NV

19. Public Comment 5:30 PM

There was no Public Comment.

20. Adjournment