

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206, Reno, NV 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

• Web Page: bop.nv.gov

### **MINUTES**

January 12-13, 2022

### **BOARD MEETING**

Pursuant to Governor Steve Sisolak's Emergency Directive 044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Hilton Garden Inn 7830 S Las Vegas Boulevard Las Vegas, NV 89123

Via Videoconference at Zoom: <a href="https://zoom.us/j/5886256671">https://zoom.us/j/5886256671</a>

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

# **Board Members Present:**

Wayne Mitchell Rolf Zakariassen Richard Tomasso

### **Board Staff Present:**

Dave Wuest	Yenh Long	Shirley Hunting	Kristopher Mangosing
Brett Kandt	Peter Keegan	Darlene Nases	Joe Dodge
Courtney Lee	Leo Basch	Ken Scheuber	Luis Curras
Dena McClish	Sarah Bradley	Rosalie Bordelove	Sophia Long

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 12 2022, 9:00 AM

There was no public comment.

# ♦ CONSENT AGENDA ◆

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of the December 1-2, 2021, Meeting Minutes (FOR POSSIBLE ACTION)

Board discussion ensued.

### Board Action:

Motion: Jade Jacobo moved to approve the December Board meeting minutes.

Second: Wayne Mitchell

<u>Action:</u> Passed unanimously.

- 4. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) Non-appearance (**FOR POSSIBLE ACTION**)
  - A. Americare Respiratory Services, Inc. Irvine, CA
  - B. Expedite LLC Lithia Springs, GA
  - C. Pumps It, Inc. Houston, TX
  - D. The Home DME Company Southfield, MI
  - 4.2 Applications for Out-of-State Wholesaler License (NRS 639.233) Non-appearance (FOR POSSIBLE ACTION)

# Background Check Not Required by Law.

- 4.2.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))
- 4.2.2 Manufacturer (NAC 639.593(7)(d))
  - E. Alydia Health, Inc. Menlo Park, CA
  - F. Aucta Pharmaceuticals, Inc. Piscataway, NJ
  - G. Avet Pharmaceuticals Inc. East Brunswick, NJ

- H. Dukal, LLC Ronkonkoma, NY
- I. Dutch Ophthalmic, USA, Inc. Exeter, NH
- J. Greenstone LLC Peapack, NJ
- K. Next Science Jacksonville, FL
- L. PharmaEssentia USA Corporation Burlington, MA
- M. University of Iowa Pharmaceuticals Iowa City, IA
- N. USAntibiotics, LLC TN
- 4.2.3 Publicly Traded (NAC 639.593(7)(a))
  - O. Haemonetics Corporation Clinton, PA
- 4.2.4 VAWD-Accredited (NAC 639.593(7)(c))
- 4.2.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))
  - P. LifeScience Logistics, LLC Brownsburg, IN
  - Q. LifeScience Logistics, LLC Whitestown, IN
- 4.2.6 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))
  - R. Adagio Therapeutics, Inc. Waltham, MA
  - S. Albireo Pharma, Inc. Boston, MA
  - T. Ortho Clinical Diagnostics, Inc. Memphis, TN
  - U. Sanofi US Corporation Bridgewater, NJ
  - V. SCYNEXIS, Inc. Jersey City, NJ
  - W. Spero Therapeutics, Inc. Cambridge, MA
- 4.2.6 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))
  - X. HP Inc. San Diego, CA

# 4.2.7 Background checks completed in compliance with NRS 639.500.

- Y. Jubilant Radiopharma Memphis, TN
- Z. RxSave Whitehall, PA
- AA. Teleflex LLC Olive Branch, MS
- BB. Teleflex LLC Plymouth, MN
- 4.3 Applications for Nevada Wholesaler License (NRS 639.233) Non-appearance (FOR POSSIBLE ACTION)
- 4.3.1 Manufacturer (NAC 639.593(7)(d))
  - CC. FH2 Pharma L.L.C Las Vegas, NV

- 4.4 Application for Nevada Pharmacy License (NRS 639.230) Non-appearance (FOR POSSIBLE ACTION)
  - DD. Omnia Pharmacy Inc. Las Vegas, NV
  - EE. QHR Pharmacy 3 Las Vegas, NV
- 4.5 Application for Nevada Compounding Pharmacy License (NRS 639.230) Non-appearance (FOR POSSIBLE ACTION)
- 4.6 Application for Out-of-State Pharmacy License (NRS 639.2328) Non-appearance (FOR POSSIBLE ACTION)
  - FF. AcariaHealth Pharmacy #26, Inc. Tampa, FL
  - GG. Allergy Partners Therapeutics Asheville, NC
  - HH. ARJ Infusion Services, LLC Lenexa, KS
  - II. ARJ Infusion Services, LLC Omaha, NE
  - JJ. Biologics by McKesson Fort Worth, TX
  - KK. Birdi Novi, MI
  - LL. CanyonCARE Rx Tempe, AZ
  - MM. Heritage Biologics LLC Lee's Summit, MO
  - NN. K Pharmacy, LLC Armonk, NY
  - OO. Lemonaid Pharmacy St. Louis, MO
- 4.7 Application for Out-of-State Compounding Pharmacy License (NRS 639.230) Non-appearance **(FOR POSSIBLE ACTION)** 
  - PP. Golden Gate Veterinary Compounding Pharmacy, LLC
  - QQ. Progress Pharmacy West Palm Beach, FL
  - RR. ReCept Pharmacy #1 Fort Worth, TX
  - SS. Summit Pharmacy, Inc. Phoenix, AZ
- 4.8 Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6942) Non-appearance (FOR POSSIBLE ACTION)
  - TT. Dia-Foot Las Vegas, NV

Board discussion ensued.

Rolf Zakariassen disclosed that he has a business relationship with the Managing Pharmacist Edward Tambi for item 4EE but stated that he could participate in this matter fairly and without bias.

Rolf Zakariassen questioned the ownership for item 4GG as the ownership change will allow a practitioner to own the company entirely which is not allowed by Nevada law.

Board staff commented that the law may be specific to practitioners licensed in Nevada, but they requested to remove item so it can be investigated further.

President Park removed item 4DD and 4GG as the Board has questions regarding the applications.

### **Board Action:**

Motion: Jade Jacobo moved to approve the Consent Agenda excluding agenda items

4DD and 4GG.

Second: Rolf Zakariassen

Action: Passed unanimously.

# ♦ REGULAR AGENDA ◆

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

A. Nevada Health Rx, Inc. dba Prax-Rx

(18-043-PH-S)

B. Scot Silber, RPH

(18-043-RPH-S)

No representative was present on behalf of Prax-Rx and Scot Silber.

Sarah Bradley, Legal Counsel for the Nevada Board of Medical Examiners, served as legal counsel to the Board.

Courtney Lee, Nevada Board of Pharmacy General Counsel, noted that failure of a party to appear upon sufficient legal notice allows the Board to proceed to consider and dispose of the case without the parties. NRS 622A.350. Ms. Lee stated that no answer was filed by either Respondent which constitutes a waiver of right to a hearing. NRS 639.244. Ms. Lee prosecuted the case against Prax-Rx and Scot Silber regarding unlawful dispensing and prescribing of dangerous drugs and controlled substances, failure to report loss of drugs, and wholesaling and dispensing without a license.

Ms. Lee called Shirley Hunting as a witness.

Shirley Hunting, Board Coordinator, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee questioned Ms. Hunting on the details of her serving the Notice of Intended Action and Accusation.

Ms. Lee requested that the proof of service for the Notice of Intended Action and Accusation be admitted as Exhibit 1.

President Park admitted Exhibit 1.

Ms. Lee called Kristopher Mangosing as a witness.

Kristopher Mangosing, Assistant Board Coordinator, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee questioned Mr. Mangosing on the details of the 21-day notices served upon Respondents.

Ms. Lee requested that the proof of service of all 21-day notices be collectively admitted as Exhibit 2.

Ms. Lee requested that the Board move to make jurisdiction consistent with paragraph 1 of the Notice of Intended Action and Accusation.

# **Board Action:**

Motion: Jade Jacobo moved to make jurisdiction consistent with paragraph 1 of the

Notice of Intended Action and Accusation as proposed by Ms. Lee.

Second: Krystal Freitas

<u>Action:</u> Passed unanimously.

Ms. Lee requested the Board to make the Findings of Fact consistent with paragraphs 2-20 of the Noticed of Intended Action and Accusation.

### **Board Action:**

Motion: Jade Jacobo moved to make Findings of Fact consistent with paragraphs 2-20

of the Notice of Intended Action and Accusation as proposed by Ms. Lee.

Second: Krystal Freitas

Action: Passed unanimously.

Ms. Lee requested the Board to make the Conclusions of Law consistent with paragraphs 21-37 of the Noticed of Intended Action and Accusation.

### **Board Action:**

Motion: Jade Jacobo moved to make the Conclusions of Law consistent with

paragraphs 21-37 of the Notice of Intended Action and Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Ms. Lee requested President Park admit the attorney's fees and investigative costs as Exhibit 3.

President Park admitted into the record the attorney's fees and costs as Exhibit 3.

Ms. Lee requested that the Board find the attorney's fees and costs of \$2,380.77 were reasonable, necessary and actually incurred.

### **Board Action:**

Motion: Wayne Mitchell moved to award the attorney's fees and costs of a \$2,380.77 on

the basis that they were reasonable, necessary and actually incurred.

Second: Rolf Zakariassen

Action: Passed unanimously.

Ms. Lee recommended the proposed discipline for Prax-Rx. The conditions/penalties include the following: 1) a fine of \$10,000 within 30 days of the Order; 2) pay \$1,785.77 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter within 30 days of the Order; 3) license was not renewed and DEA registration was surrendered; if Prax-Rx seeks to obtain another license, Prax will be required to appear before the Board for approval; and 4) discipline will be reportable to the National Practitioner Data Bank.

Board discussion ensued.

#### **Board Action:**

Motion: Jade Jacobo moved to approve the proposed discipline as presented by Ms.

Lee.

Second: Wayne Mitchell

<u>Action:</u> Passed unanimously.

Ms. Lee recommended the proposed discipline for Scot Silber. The conditions/penalties include the following: 1) a fine of \$5,000 within 30 days of the Order; 2) pay \$595 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter within 30 days of the Order; 3) discipline will be reportable to the National Practitioner Data Bank; and 4) Mr. Silber voluntarily surrendered his pharmacist

registration; Silber may not re-apply for reinstatement for a minimum of two years and must appear before the Board for approval.

Board discussion ensued.

# **Board Action:**

Motion: Jade Jacobo moved to approve the proposed discipline as presented by Ms.

Lee.

Second: Rolf Zakariassen

Action: Passed unanimously.

C. Stephen Dubin, MD (20-020-CS-S)

This matter was continued to a future Board Meeting.

D. James Forsythe, MD, HMD (19-114-CS-N)

Marie Mirch appeared as counsel on behalf of James Forsythe.

James Forsythe was present for the hearing.

James Forsythe, Manon Singer (Infusion Nurse), and Valerie Kilgore (Office Manager) appeared and were sworn in by President Park.

President Park stated that Respondent filed a motion to dismiss the amended accusation or alternatively for a more definite statement, and the State filed an opposition to the motion.

President Park ruled to deny the motion to dismiss and proceed with the hearing.

Brett Kandt made an opening statement on the charges that Dr. Forsythe's practice had expired drugs and a "veterinary use only" drug in its inventory.

Mr. Kandt called Joseph Depczynski, retired Nevada State Board of Pharmacy Investigator, as a witness.

Mr. Depczynski appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Kandt examined Mr. Depczynski on his investigation and upon foundation testimony from the witness requested that the following exhibits be entered into evidence: 1) documents bate-stamped 001-007 as Exhibit 1; 2) documents bate-stamped 008-009 as Exhibit 2; 3) documents bate-stamped as 0010-0011 as Exhibit 3; 4) documents bate-stamped as 0012 as

Exhibit 4; 5) documents bate-stamped 0015-0016 as Exhibit 5; 6) documents bate-stamped as 0017-0018 as Exhibit 6; 7) documents bate-stamped 0019 as Exhibit 7.

Ms. Mirch objected to the exhibits for pages 002-003, 005-007, 008-009, 0015-0016, 0017-0018. President Park overruled the objections and admitted Exhibits 1-7 into evidence.

Rosalie Bordelove, Chief Deputy Attorney General, appeared as Board counsel for this hearing, and Sarah Bradley was excused from the meeting at 10:30 AM.

Ms. Mirch cross-examined Mr. Depczynski, and the Board questioned Mr. Depczynski.

Ms. Mirch called Manon Singer, Dr. Forsythe's Infusion Nurse, as a witness.

Ms. Mirch examined Ms. Singer on her position and the events that occurred with the Board's investigation. Mr. Kandt cross-examined Ms. Singer, and the Board questioned Ms. Singer.

Ms. Mirch called Valerie Kilgore, Dr. Forsythe's Office Manager, as a witness.

Ms. Mirch examined Ms. Kilgore on her position and the events that occurred with the Board's investigation.

Ms. Mirch requested that a proposed exhibit labeled Forsythe Exhibit 12 be entered into evidence as Exhibit 12.

Mr. Kandt objected that there was no foundation for admission of the evidence. President Park overruled the objection and admitted Exhibit 12 into evidence after further foundation testimony by Ms. Kilgore.

Ms. Mirch requested that a proposed exhibit labeled Forsythe Exhibit 11 pages 1-2 be entered into evidence as Exhibit 11 after foundation testimony by Ms. Kilgore. Kandt had no objection and President Park admitted Exhibit 11 into evidence.

Ms. Mirch requested that a proposed Exhibit 8 be entered into evidence. Mr. Kandt objected that the evidence was not relevant or material and lacked any probative value. President Park sustained the objection and denied admission.

Mr. Kandt cross-examined Ms. Kilgore, and the Board questioned Ms. Kilgore.

Ms. Kilgore confirmed that the pictures taken were staged, and the cabinet in the picture was not the cabinet that held the expired dangerous drugs.

Ms. Mirch requested that the remainder of Forsythe Exhibit 11 pages 3-5 be entered into evidence after foundation testimony by Ms. Kilgore. Kandt had no objection and President Park admitted pages 3-5 of Forsythe Exhibit 11 into evidence.

Sophia Long, Senior Deputy Attorney General, appeared as Board counsel for this hearing, and Rosalie Bordelove was excused from the meeting at 1:30 PM.

Ms. Mirch called George Ransom as a witness.

George Ransom, Retired Certified Public Accountant, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Mirch questioned Mr. Ransom about Dr. Forsythe's inventory control system.

Mr. Kandt objected that Mr. Ransom's testimony on Dr. Forsythe's inventory control system subsequent to the investigation was not relevant or material and lacked any probative value.

President Park sustained the objection and there was no further testimony from Mr. Ransom.

Ms. Mirch called Amy Summers as a witness.

Amy Summers, Registered Pharmacist appeared and was sworn in by President Park prior to answering questions and offering testimony. Mr. Kandt stipulated that Ms. Summers qualified as an expert.

Ms. Mirch questioned Ms. Summers on her findings concerning Dr. Forsythe's practice.

Mr. Kandt objected that Ms. Summers testimony was not relevant or material and lacked any probative value as she was hired after the charges were filed against Dr. Forsythe.

President Park sustained the objection and advised Ms. Mirch to limit her questions to the timeframe in question.

The Board questioned Ms. Summers.

Ms. Mirch called Dr. James Forsythe as a witness.

Ms. Mirch examined Dr. Forsythe on his practice and the allegations against him. Mr. Kandt cross-examined Dr. Forsythe, and the Board questioned Dr. Forsythe.

Ms. Mirch and Mr. Kandt provided their closing arguments to the Board on this hearing.

Board discussion ensued.

Mr. Kandt requested that the Board make findings of fact consistent with paragraphs 1-5 of the First Amended Notice of Intended Action Accusation

### **Board Action:**

Motion: Richard Tomasso moved to make findings of fact consistent with paragraphs 1-

5 of the First Amended Notice of Intended Action and Accusation.

Second: Jade Jacobo

<u>Action:</u> Passed unanimously.

Mr. Kandt requested that the Board make conclusions of law consistent with paragraphs 6-17 of the First Amended Notice of Intended Action and Accusation and find Dr. Forysthe guilty of all four causes of action.

# **Board Action:**

Motion: Jade Jacobo moved to make conclusions of law consistent with paragraphs 6-

17 of the First Amended Notice of Intended Action and Accusation and find Dr.

Forsythe guilty of all four Causes of Action.

Second: Richard Tomasso

<u>Action:</u> Passed unanimously.

Gener Tejero joined the meeting by telephone at 4:36 PM.

Mr. Kandt provided documentation of attorney's fees and costs totaling \$2,384.08 and requested that it be entered into evidence as Exhibit 9.

Ms. Mirch objected to any attorney's fees and costs prior to filing of the amended accusation.

Mr. Kandt responded that the attorney's fees and costs are very reasonable and do not account for his extra time worked on this case or Mr. Depczynski's time investigating the case.

President Park admitted the documentation of attorney's fees and costs into evidence as Exhibit 9.

Mr. Kandt requested that the Board find that the attorney's fees and costs of \$2,384.08 were reasonable, necessary and actually incurred.

## **Board Action:**

Motion: Jade Jacobo moved to award the attorney's fees and costs of \$2,348.08 on the

basis that they were reasonable, necessary and actually incurred.

Second: Wayne Mitchell

Action: Passed unanimously.

Mr. Kandt proposed the following penalties for Dr. Forsythe: 1) public reprimand; 2) respondent pay a \$2,000 fine for each of the four causes of action within 30 days; 3) respondent pay \$2,348.08 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter within 30 days, order effective immediately.

Ms. Mirch requested that the Board take into consideration the costs that Dr. Forsythe incurred for expert witnesses and attorney's fees, and further argued that the fine recommended is excessive and opposed a public reprimand and reporting the discipline to the National Practitioner Data Bank.

Board discussion ensued regarding appropriate penalties.

# **Board Action:**

Motion: Richard Tomasso moved to approve the following penalties for Dr. Forsythe: 1)

public reprimand; 2) respondent pay a \$5,000 fine for the four causes of action, for a total of \$20,000, within 30 days; 3) respondent pay \$2,348.08 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter within 30 days; 4) board staff conduct an inspection of Dr. Forsythe's Office within 30 days; and 5) order effective

immediately.

Second: Wayne Mitchell

Aye: Jacobo, Tomasso, Mitchell, Zakariassen

Nay: Park, Tejero, Freitas

Action: Motion carries.

E. Chad Hall, DO (21-108-CS-S)

This matter was continued to a future Board Meeting.

F. Ronald Smith, MD (20-212-CS-S)

This matter was continued to a future Board Meeting.

G. Kord T. Strebel, MD (19-053-CS-S)

This matter was continued to a future Board Meeting.

H. Thomas E. Strebel, RPH (19-053-RPH-S)

This matter was continued to a future Board Meeting.

I. Sircy M. Moore, DVM

(21-111-CS-S)

This matter was continued to a future Board Meeting.

6. Appeal hearing pursuant to NRS 639.2895(2) (**FOR POSSIBLE ACTION**)

A. Sandra Bledsoe. D/B/A VIP Faces

(21-042-S)

This matter was continued to a future Board Meeting.

B. Sandra Bledsoe, D/B/A Revenge MD

(21-042-B-S/21-042-C-S)

This matter was continued to a future Board Meeting.

Public Comment January 12 2022, 5:00 PM

Jeffrey Setness wanted to discuss his scheduling for his agenda item.

John Hunt wanted to discuss his scheduling for his agenda item.

Board staff commented that they can contact Mr. Kandt to discuss the scheduling.

President Park recessed the meeting for the night and reconvened the meeting the next morning and performed the roll call. All Board members were present and a quorum was established.

### **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 Kristopher Mangosing

Brett Kandt Peter Keegan Darlene Nases Joe Dodge Courtney Lee Leo Basch Ken Scheuber Luis Curras

Dena McClish Christian Schonlau Rosalie Bordelove

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.

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.

Public Comment January 13 2022, 9:00 AM

Joseph Hardy, Nevada Senator, wants to make comments regarding Workshop Item 24B.

Board staff advised that his comments can be made when the item is addressed.

# ♦ WORKSHOP ♦

### Thursday January 13, 2022 – 9:00 am

- 24. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2) (FOR POSSIBLE ACTION):
  - B. Amendment to Nevada Administrative Code (NAC) 453B. The proposed amendments conform the outdated language of NAC 453B to the changes made to NRS 453B in 2017 by Senate Bill 91. Specifically, the proposed changes to NRS 453B broaden the previously established Cancer Drug Donation Program to include prescription drugs generally. The proposed amendments also define "donated prescription drug" and establish requirements for a person or a pharmacy to participate in the Prescription Drug Donation Program.

Dave Wuest, Executive Secretary for the Nevada Board of Pharmacy, provided background on the workshop item.

Yenh Long, Deputy Secretary for the Nevada Board of Pharmacy, provided the proposed language changes.

President Park opened public comment for this proposed regulation.

Joseph Hardy, Nevada Senator, commented that he worked with Board staff on the language and is in favor of the proposed regulation.

Samantha Chessie from Animal Policy Group questioned how this regulation may affect donated prescription drugs for veterinarian drugs.

Ms. Long provided clarification to Ms. Chessie as it will not affect veterinarian laws.

Liz McMenamin from the Retail Association of Nevada in favor of the proposed regulation. However, she is concerned about who the liability of the drugs falls on.

Mr. Hardy commented that this bill will protect everyone involved and will help others in need of medicine.

Board discussion ensued.

# **Board Action:**

Motion: Jade Jacobo moved to adopt the proposed regulation for Amendment to

Nevada Administrative Code (NAC) 453B and move to public hearing.

Second: Wayne Mitchell

Action: Passed unanimously.

A. Amendment of Nevada Administrative Code (NAC) 453.510: Schedule I. The proposed amendment to NAC 453.510 will add isotonitazene to the list of controlled substances listed in Schedule I.

Ms. Long provided background and the proposed language changes.

President Park opened public comment for this proposed regulation.

There was no public comment.

Board discussion ensued.

#### **Board Action:**

Motion: Jade Jacobo moved to adopt the proposed regulation for Amendment of

Nevada Administrative Code (NAC) 453.510: Schedule I and moved to public

hearing.

Second: Krystal Freitas

Action: Passed unanimously.

### ◆ PUBLIC HEARING ◆

## <u>Thursday January 13, 2022 – 9:00 am</u>

25. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2) (FOR POSSIBLE ACTION):

A. Amendment of Nevada Administrative Code (NAC 639). The proposed amendments will add a new section to implement the provisions of Senate Bill 190, requiring the Board to adopt regulations that establish a protocol to allow a pharmacist to dispense a self-administered hormonal contraceptive to any patient. (LCB File R036-21)

Courtney Lee, Nevada Board of Pharmacy General Counsel, provided background on the proposed regulation.

President Park opened public comment for this public hearing item.

Ken Kunke from the Nevada Pharmacy Alliance commented that a registered pharmacist at doctor's office do not qualify for this regulation and would like this updated to have them included.

Lauren Paul from CVS Health commented her concerns and provided the following proposed changes: 1) requiring the pharmacy, and not the pharmacist, to report their intent to dispense self-administered hormonal contraceptives; 2) requiring pharmacist to complete one hour of continuing education, instead of two, in order to dispense self-administered hormonal contraceptives; 3) allowing a pharmacist to assess or evaluate a patient's blood pressure from the electronic health record or obtained the blood pressure by the pharmacist prior to dispensing self-administered hormonal contraceptives.

Adam Porath from Nevada Health System Pharmacists would like the language to include pharmacist who do not work in a dispensing role, but he is okay to address this issue later.

Liz McMenamin from the Retail Association of Nevada is in favor of the language and is okay to address the concerns later.

Board staff addressed comments and concerns of the public regarding the proposed regulation and the process of the language going to Legislative Counsel Bureau (LCB).

Adam Chesler from VillageMD requested the patient be provided with a list of providers that dispense self-administered hormonal contraceptives. In addition, he suggested that a process be in place to provide the records to the patient's primary care provider.

Ms. Long commented to the Board that a written statement from Krystal Riccio was provided for this public hearing item.

Krystal Riccio from Roseman University provided a written statement and asked the Board to consider allowing qualified pharmacists practicing outside of a licensed pharmacy to dispense or prescribe hormonal contraceptives.

Board discussion ensued.

# **Board Action:**

Motion: Jade Jacobo moved to adopt regulation for Amendment of Nevada

Administrative Code (NAC 639) with amendments to modify CE requirement

to one hour and to modify blood pressure language to evaluate as

discussed.

Second: Krystal Freitas

Action: Passed unanimously.

B. Amendment of Nevada Administrative Code (NAC) 639.501 Inspections; provision of self-assessment form. The proposed amendment to NAC 639.501 will remove the requirement to complete an assessment of workplace and modifies the requirement of an annual inspection. (LCB File R165-20)

Mr. Wuest provided background on the proposed regulation.

President Park opened public comment for this public hearing item.

Liz McMenamin from Retail Association of Nevada is in support of the proposed language.

Board discussion ensued.

#### **Board Action:**

Motion: Jade Jacobo moved to adopt proposed regulation for Amendment of Nevada

Administrative Code (NAC) 639.501 Inspections; provision of self-assessment

form.

Second: Wayne Mitchell

Action: Passed unanimously.

16. Applications for Out-of-State Wholesaler License (NRS 639.233) – Appearance (**FOR POSSIBLE ACTION**)

A. Atrium Medical Corporation – Merrimack, NH – Background Check Not Required - Manufacturer (NAC 639.593(7)(d)) – Disclosure

Chad Carlton, President, and Brian Schaeffer, Quality Engineer, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Peter Keegan, Nevada Board of Pharmacy General Counsel, provided background on application and their disclosures regarding shipping products without proper licensure and being fined by the FDA for selling adulterated drugs.

The Board questioned Atrium about the last inspection results and what occurred with their disclosure regarding the FDA.

Mr. Carlton and Mr. Schaeffer answered questions to the Board's satisfaction

Board discussion ensued.

# **Board Action:**

Motion: Gener Tejero moved to approve Out-of-State Wholesaler license for Atrium

Medical Corporation pending staff's review of their 483 FDA Inspection and

their corrective action plan.

Second: Jade Jacobo

<u>Action:</u> Passed unanimously.

B. Baxter Healthcare Corporation – Byhalia, MS – Background Check Not Required – VAWD-Accredited (NAC 639.593(7)(c)) – Disclosure

Lawrence Davis, Senior Quality Manager, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Katrina Reinhardt, Regulatory Deputy Counsel, appeared as counsel on behalf of Baxter Healthcare Corporation.

Mr. Wuest provided background on application and their disclosures regarding not correctly addressing mold at a manufacturing facility, improperly delegating final verification of prescriptions to a pharmacy technician, not notifying of a change in a timely manner, operating without a license, and selling prescriptions to an unpermitted location.

Ms. Reinhardt provided further clarification on disclosures to the Board.

Board discussion ensued.

### Board Action:

Motion: Wayne Mitchell moved to approve Out-of-State Wholesaler license for Baxter

Medical Corporation.

Second: Rolf Zakariassen

# Action: Passed unanimously.

- C. Hilco Vision Plainville, MA Background Check completed in compliance with NRS 639.500 No Disqualifying Events Disclosure
- D. Hilco Vision Tucson, AZ Background Check completed in compliance with NRS 639.500 No Disqualifying Events Disclosure

Rebecca Davis (Senior Regulatory Affairs) Jon Costa (Senior Operations Manager), Ken Miranda (Chief Operating Manager), Charles Hick (Distribution Manager) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee provided background on application and disclosures regarding operating without the proper licensure and reciprocal action taken by another Board.

Ms. Lee questioned Hilco Vision on changes that occurred within the company to ensure that they remain compliant.

Mr. Costa and Mr. Miranda answered questions to the Board's satisfaction.

Board discussion ensued.

# **Board Action:**

Motion: Wayne Mitchell moved to approve the Out-of-State Wholesaler change on

ownership (CHOW) application for Hilco Vision in Plainville, MA and Tucson,

AZ.

Second: Jade Jacobo

Action: Passed unanimously.

- 13. Applications for Out-of-State Pharmacy License (NRS 639.2328) Appearance (**FOR POSSIBLE ACTION**)
  - A. Amazon Pharmacy #005 Kent, WA
  - B. Amazon Pharmacy #006 Indianapolis, IN
  - C. Amazon Pharmacy #007 Meridian, ID

Emily Haugh, Pharmacist and Government Affairs Manager, and Chris Rochon, Senior Compliance Manager, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Keegan requested a Letter of Authorization from Ms. Haugh and Mr. Rochon to allow them to speak on behalf of the company.

Mr. Keegan provided background on the application and their disclosures regarding operating without the proper licensure.

The Board questioned Amazon Pharmacy on what changes have occurred to ensure that they are compliant.

Ms. Haugh and Mr. Rochon answered questions to the Board's satisfaction.

Board discussion ensued.

# **Board Action:**

Motion: Krystal Freitas moved to approve the Out-of-State Pharmacy license for

Amazon Pharmacy #005, Amazon Pharmacy #006, and Amazon Pharmacy

#007 pending Letter of Authorization.

Second: Jade Jacobo

<u>Action:</u> Passed unanimously.

D. DiRx - Sunrise, FL

Briana Moe, Pharmacist in Charge, appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park requested a Letter of Authorization for Ms. Moe to speak on behalf of the company.

Joe Dodge, Nevada Board of Pharmacy Inspector, provided background on the application and their disclosures regarding not being properly licensed, sending prescriptions to the incorrect primary care physician, and failure to disclose disciplinary action on an application,

Mr. Dodge questioned Ms. Moe about the business model, inspection results, and further clarification of what occurred with their disclosures.

Ms. Moe answered questions to the Board's satisfaction.

Board discussion ensued.

### **Board Action:**

Motion: Jade Jacobo moved to approve change of ownership for Out-of-State

Pharmacy license for DiRx.

Second: Rolf Zakariassen

Action: Passed unanimously.

- Application for Out-of-State Compounding Pharmacy License (NRS 639.230) –
  Appearance (FOR POSSIBLE ACTION)
  - A. Dynamic Rx Labs LLC Renton, WA

James Axtell (Co-founder and Co-Owner), and Quan Pho (Part-Owner and Pharmacist), and Angelique Williams (Pharmacist in Charge) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Chris Dang appeared as counsel on behalf of Dynamic Rx Labs.

Mr. Dodge provided background on application, their inspection results, and their disclosure regarding pharmacy technicians in training's registrations lapsing.

Mr. Dodge questioned Dynamic Rx on the change of ownership, experience of the pharmacist in charge, their business model, and their disclosures.

Mr. Axtell, Mr. Dang, and Ms. Williams answered questions to the Board's satisfaction.

# **Board Action:**

Motion: Jade Jacobo moved to approve change of ownership for Out-of-State

Compounding Pharmacy license for Dyanmic Rx Labs.

Second: Wayne Mitchell

Action: Passed unanimously.

B. Soleo Health Inc. – Dublin, OH

Jason Doenges, Pharmacist in Charge, appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park requested a Letter of Authorization for Mr. Doenges to speak on behalf of the company.

Mr. Dodge provided background on application and disclosures regarding disorderly conduct.

Mr. Dodge questioned about the business model, products, inspection results, and Mr. Doenges disclosure.

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

Board discussion ensued.

# **Board Action:**

Motion: Jade Jacobo moved to approve Out-of-State Compounding Pharmacy License

for Soleo Health Inc. pending Letter of Authorization.

Second: Gener Tejero

Action: Passed unanimously.

15. Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance (**FOR POSSIBLE ACTION**)

Eclipse Mobility, LLC – Bountiful, UT

Landon Cleverly, Operations Director, and Travis Carlson, Managing Member, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Ms. Long provided background on application and their disclosure regarding a family member possessing or using a controlled substance.

Ms. Long questioned on the business model, Mr. Cleverly's experience with the products, and further clarification on their disclosure.

Mr. Cleverly and Mr. Carlson answered questions to the Board's satisfaction.

Board discussion ensued.

#### Board Action:

Motion: Krystal Freitas moved to approve Out-of-State Medical, Devices, Equipment

and Gases License for Eclipse Mobility, LLC.

Second: Jade Jacobo

<u>Action:</u> Passed unanimously.

7. Petition for Reinstatement of Unrestricted Controlled Substance Registration pursuant to NRS 639.257

Craig Weingrow (17-066-CS-S)

Jeffrey Setness appeared as counsel on behalf of Craig Weingrow.

Craig Weingrow appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Setness is petitioning for reinstatement for Dr. Weingrow's unrestricted controlled substance registration.

Mr. Kandt provided background on charges for Dr. Weingrow to Board.

The Board questioned Dr. Weigrow on his probation status and his business model.

Dr. Weingrow answered questions to the Board's satisfaction.

Board discussion ensued.

Mr. Setness commented that Dr. Weingrow plans to prescribe only the drugs listed on his original Board Order. The only reason that he is applying for an unrestricted license is for insurance purposes.

Board discussion ensued.

# Board Action:

Motion: Gener Tejero moved to fully reinstate Dr. Craig Weingrow's Controlled

Substance registration with conditions that he submits self-reports quarterly of every prescribed controlled substance prescription for five years from the date

of Order.

Second: Jade Jacobo

<u>Aye:</u> Park, Jacobo, Freitas, Tejero, Tomasso, Zakarissen

Nay: Mitchell

Action: Motion carries.

- 12. Application for Nevada Pharmacy License (NRS 639.230) Appearance (**FOR POSSIBLE ACTION**)
  - A. Canyonlands Healthcare Mesquite, NV

Andrew Lewandowski, Pharmacy Director, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background on application.

Mr. Dodge questioned on the business model and Mr. Lewandowski's experience, and future for the pharmacy.

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

Board discussion ensued.

# **Board Action:**

Motion: Jade Jacobo moved to approve Nevada Pharmacy License for Canyonlands

Healthcare pending favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

B. Complete Care Pharmacy – Las Vegas, NV

This matter was continued to a future Board Meeting.

17. Applications for Nevada Wholesaler License (NRS 639.233) – Appearance (**FOR POSSIBLE ACTION**)

A. Compass Health Brands Corp. – Reno, NV – Background Check completed in compliance with NRS 639.500 - No Disqualifying Events – No Disclosures

Jason Derbyshire, Facility Manager for Reno, and Anthony Shaw, Vice President of Quality, Regulatory, and Customer Service, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Keegan provided background on application.

The Board questioned Mr. Derbyshire and Mr. Shaw on the business model, the products being shipped into Nevada, and Mr. Derbyshire's experience.

Mr. Shaw and Mr. Derbyshire answered questions to Board's satisfaction.

The Board staff requested an updated Designated Representative application to accurately reflect his experience with pharmacies or wholesalers.

Board discussion ensued.

#### **Board Action:**

Motion: Jade Jacobo moved to approve Nevada Wholesaler License for Compass

Health Brands Corp. pending updated Designated Representative application.

Second: Gener Tejero

Action: Passed unanimously.

B. J.W. Welding Supplies and Tools – Fallon, NV – Background Check Not Required - Manufacturer (NAC 639.593(7)(d)) – No Disclosures

John Craig, Owner, and Ben Craig, Fallon Facility Manager, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Wuest provided background on application.

Mr. Wuest questioned Mr. Craig on the business model and products being shipped into Nevada.

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

Board discussion ensued.

# **Board Action:**

Motion: Jade Jacobo moved to approve Nevada Wholesaler License for J.W. Welding

Supplies and Tools.

Second: Rolf Zakariassen

<u>Action:</u> Passed unanimously.

19. Request for Pharmacist Applicant to Retake the NAPLEX Exam (NRS 639.120(1)) – Appearance: **(FOR POSSIBLE ACTION)** 

A. Bea Belarmino

Bea Belarmino appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Belarmino provided background on her appearance before the Board regarding another chance to take the NAPLEX exam.

The Board questioned Ms. Belarmino about her education and what she does to prepare for her exams.

Ms. Belarmino answered the questions to the Board's satisfaction.

Board discussion ensued.

# **Board Action:**

Motion: Richard Tomasso moved to approve Bea Belarmino to take one more attempt

at the NAPLEX exam.

Second: Jade Jacobo

Board staff asked Ms. Belarmino the disclosure questions on the Application by Examination and stated that a new application must be submitted every time a person takes the NAPLEX exam.

Ms. Belarmino answered "no" to all questions asked.

<u>Action:</u> Passed unanimously.

C. Tsigereda Mulugeta

Tsigereda Mulugeta appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Mulugeta provided background on her appearance before the Board regarding another chance to take the NAPLEX exam.

Board discussion ensued.

#### Board Action:

Motion: Jade Jacobo moved to approve Tsigereda Mulugeta to take one more attempt

at the NAPLEX exam.

Second: Krystal Freitas

Board staff asked Ms. Mulugeta the disclosure questions on the Application by Examination and stated that a new application must be submitted every time a person takes the NAPLEX exam.

Ms. Mulugeta answered "no" to all questions asked.

Action: Passed unanimously.

23. Executive Secretary Report:

# A. Financial Report

Christian Schonlau, Nevada Board of Pharmacy Chief Financial Officer, provided the financial report to the Board's satisfaction.

Board discussion ensued.

- 19. Request for Pharmacist Applicant to Retake the NAPLEX Exam (NRS 639.120(1)) Appearance: **(FOR POSSIBLE ACTION)** 
  - B. Arnold Castro

Arnold Castro appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Castro provided background on his appearance before the Board regarding another chance to take the NAPLEX exam.

The Board questioned Mr. Castro on if he has ever been licensed in Nevada, his disclosure that was dismissed, and why he wants to take the NAPLEX again.

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

Mr. Wuest commented that Richard Tomasso and Krystal Freitas were excused from the meeting and returned around 2:45 PM.

Board discussion ensued.

#### Board Action:

Motion: Wayne Mitchell moved to approve Arnold Castro to take one more attempt at

the NAPLEX exam.

Second: Richard Tomasso

Action: Passed unanimously.

8. Petition for Reconsideration of Denial of Controlled Substance Registration pursuant to NRS 639.139. **(FOR POSSIBLE ACTION)** 

Victor Bruce

Rosalie Bordelove, Counsel for the Board, joined the meeting at 3:00 PM.

Victor Bruce appeared and was sworn in by President Park prior to answering questions and offering testimony.

John Hunt appeared as counsel on behalf of Dr. Bruce.

Mr. Kandt provided background on appearance regarding a petition for reconsideration of denial for Dr. Bruce's controlled substance registration.

Mr. Hunt commented that he provided a list of drugs that Dr. Bruce is requesting the Board to consider allowing him to have a controlled substance license with conditions.

Board discussion ensued.

# **Board Action:**

Motion:

Jade Jacobo moved to approve controlled substance registration for Dr. Victor Bruce with conditions that he is only able to prescribe from the list provided with the removal of Phentermine Hydrochloride, Tylenol with Codeine, Human Growth Hormone (HGH), and remove Neurontin and to modify Testosterone Cypionate to "Testosterone". In addition, Dr. Bruce will self-report monthly of the controlled substances that he prescribes from MyRx and must notify the Board immediately if he encounters any discrepancies.

Mr. Kandt suggested that motion be amended to include correct language.

Jade Jacobo amended her motion as recommended by Mr. Kandt.

Motion:

Jade Jacobo moved to grant Dr. Victor Bruce's petition and to approve issuance of a controlled substance registration with the following conditions: 1) Dr. Bruce is only able to prescribe from the list provided with the removal of Phentermine Hydrochloride, Tylenol with Codeine, Human Growth Hormone (HGH), and Neurontin; 2) Modify the drug list for Testosterone Cypionate and change to "Testosterone"; 3) Dr. Bruce will self-report monthly the controlled substances that he prescribes from MyRx and must notify the Board immediately if he encounters any discrepancies.

Second: Richard Tomasso

<u>Action:</u> Passed unanimously.

9. Application for Pharmacist Registration Renewal (NRS 639.127) – Appearance. (FOR POSSIBLE ACTION)

Darrel Foth

This matter was continued to a future Board Meeting.

10. Application for Pharmacist Registration by Reciprocation NRS 639.134) – Appearance (**FOR POSSIBLE ACTION**)

Eric Galey

Eric Galey appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Keegan provided background on the application and his disclosures regarding using beyond use date drugs when compounding and misfiled a prescription.

Mr. Galey provided clarification of his disclosure to Board and reasons for requesting licensure in Nevada.

Board discussion ensued.

# **Board Action:**

Motion: Rolf Zakariassen moved to approve Application for Pharmacist Registration by

Reciprocation for Eric Galey.

Second: Wayne Mitchell

<u>Action:</u> Passed unanimously.

11. Application for Veterinarian Authority to Dispense Drugs (NAC 639.7423) – Appearance (FOR POSSIBLE ACTION)

A. Lesli Ann Hewitt-Spears

Lesli Ann Hewitt-Spears appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee provided background on the application and disclosure regarding public reprimand due to missing drugs at her veterinary office.

The Board questioned Ms. Hewitt-Spears on what she plans to dispense, her reason for requesting a license, and what occurred with her disclosure.

Ms. Hewitt-Spears answered questions to the Board's satisfaction. She disclosed that she dispensed drugs prior to having a license and her office assistant occasionally assisted with the dispensation of drugs. She further clarified that she personally dispensed the controlled substances in her practice.

Board discussion ensued.

# **Board Action:**

Motion: Jade Jacobo moved to approve Veterinarian Authority to Dispense Drugs

Registration for Lesli Ann Hewitt-Spears pending favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

B. Sircy Moore

This matter was continued to a future Board Meeting.

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

Comprehensive Surgical Care of Reno-Tahoe, LLC - Reno, NV

Erin Brown (Administrator), Brian Evans (Medical Director), Joel Rainwater (Chief Medical Officer), Lovnit Kaur (Pharmacist Consultant), and Carleen Cordova (Compliance Officer) appeared and were sworn in by President Park prior to answering questions and offering testimony.

President Park disclosed that she knows Lovnit Kaur through Roseman University but stated that she could participate in this matter fairly and without bias.

Mr. Dodge provided background on application.

The Board questioned about the services being provided, what is Ms. Kaur's role, and who is the emergency contact at the location.

Ms. Kaur and Mr. Evans answered questions to the Board's satisfaction.

Mr. Dodge commented that one of the owners noted a disclosure on their Personal History application regarding two public reprimands by the Nevada Board of Medical Examiners.

Dr. Charles Virden appeared and was sworn in by President Park prior to answering questions and offering testimony.

The Board guestioned Dr. Virden about the events that occurred with his disclosures.

Dr. Virden answered to the Board's satisfaction.

Board discussion ensued.

# Board Action:

Motion: Jade Jacobo moved to approve Ambulatory Surgery Center License for

Comprehensive Surgical Care of Reno-Tahoe, LLC pending favorable

inspection.

Second: Richard Tomasso

Action: Passed unanimously.

18. Request to Engage in the Practice of Pharmacy at a Site Other than a Licensed Pharmacy – Appearance (FOR POSSIBLE ACTION)

Anja Palazova

Anja Palazova appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Wuest provided background on appearance regarding Ms. Palazova requesting a to participate in the practice of pharmacy at site other than licensed pharmacy.

The Board questioned about her role and what her plans are with Aspen Rx Health.

Ms. Palazova answered questions to the Board's satisfaction.

Board discussion ensued.

#### Board Action:

Motion: Gener Tejero moved to approve Anja Palazova's request to engage in the

practice of pharmacy at a site other than a licensed pharmacy at AspenRx

Health for the services listed in the application.

Second: Jade Jacobo

Action: Passed unanimously.

21. Discussion and Possible Action on Adoption of Emergency Regulation pursuant to NRS 233B.0613 to authorize pharmacists and other healthcare professionals to dispense oral medications for the treatment of COVID-19 subject to certain conditions. (FOR POSSIBLE ACTION)

This matter was continued to a future Board Meeting.

22. 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).

General Counsel had no items to report for this matter.

- 23. Executive Secretary Report:
  - B. Issuance of Temporary Licenses and Registrations
  - C. Change of Address Business List
  - D. Meetings with Other Health Care Regulatory Boards
  - E. COVID-19 Response
  - F. Licensing Software Update
  - G. Licensing Activities Report
  - H. PMP Integration

Mr. Wuest provided Executive Secretary Report to the Board's satisfaction.

Board discussion ensued.

26. Date and Location of Next Scheduled Board Meeting:

March 2-3, 2022 - Zoom

27. Public Comment January 13 2022, 5:00 PM

There was no public comment.

28. Adjournment