NEVADA STATE BOARD OF PHARMACY

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MINUTES

March 1, 2017

BOARD MEETING.

Hyatt Place 1790 E Plumb Lane Reno, Nevada

Board Members Present:

Leo Basch Kevin Desmond Jason Penrod Tallie Pederson

Robert Sullivan Kirk Wentworth Darla Zarley

Board Staff Present:

Larry Pinson Dave Wuest Paul Edwards Shirley Hunting

Joe Depczynski Peter Keegan Kristopher Mangosing

Mr. Pinson stated that a representative from Pinnacle Compounding Pharmacy (Item 11) contacted Board Staff to reschedule their appearance until the April 2017 board meeting.

1. Public Comment March 1, 2017 9:00 AM

There was no public comment.

2. Approval of January 11, 2017, Minutes

Tallie Pederson recused from participation in this matter due to her absence from the January 11, 2017 board meeting.

Mr. Pinson stated that Board Staff discovered two errors in the January 11, 2017 Meeting Minutes. On pg. 1 the meeting date has been corrected from January 11, 2016 to January 11, 2017. On pg. 13 (Executive Secretary Report) the Minutes have been corrected to reflect Robert Sullivan as the Delegate for the NABP Annual Meeting and Jason Penrod volunteered to be the alternate.

Board Action:

Motion: Jason Penrod moved to approve the January 11, 2017 Meeting Minutes with

corrections as noted.

Second: Darla Zarley

Action: Passed unanimously

3. Approval of January 26, 2017, Minutes

Kirk Wentworth recused from participation in this matter due to his absence from the January 26, 2017 board meeting.

Board Action:

Motion: Jason Penrod moved to approve the January 26, 2017 Meeting Minutes as

presented.

Second: Darla Zarley

Action: Passed unanimously

4. Applications for Out-of-State Pharmacy – Non Appearance:

- A. Allivet Hialeah, FL
- B. Bowie's Priority Care Pharmacy, LLC Jasper, AL
- C. Delaney Pharmacy, LLC Lexington, TX
- D. Fusion Pharmaceuticals Tampa, FL
- E. Hawthorne Pharmacy, LLC Hamilton, OH
- F. Innovative RX, LLC Draper, UT
- G. Pinnacle Pharmacy Solutions, LLC Tempe, AZ
- H. Prime Therapeutics Specialty Pharmacy Orlando, FL
- I. Scripts Rx Pharmacy Chicago, IL
- J. US Healthlink, LLC Orlando, FL
- K. Walgreens #02445 Orlando, FL
- L. Wellness Pharmacy, LLC Houston, TX

Applications for Out-of-State Compounding Pharmacy – Non Appearance:

- M. Advanced Rx East Norriton, PA
- N. Carecom Pharmacy & Compounding Katy, TX
- O. CareRxLLC/PayLess Drug Vancouver, WA
- P. Loyola Pharmacy Los Angeles, CA
- Q. Prime Therapeutics Irving, TX
- R. Walgreens Mail Service Tempe, AZ

Applications for Out-of-State Wholesaler – Non Appearance:

S. AmerisourceBergen Drug Coro – Phoenix, AZ

- Т. Avella of Deer Valley, Inc. #38 – Phoenix, AZ
- U. Cardinal Health 200 LLC - Grand Prairie, OH
- ٧. Curascript SD Specialty Distribution – Memphis, TN
- W. Flexion Therapeutics, Inc. – Burlington, MA
- Χ. Fresenius Medical Care North America - Concord, CA
- Y. Fresenius Medical Care North America – DFW Airport, TX
- Z. Hercules Pharmaceuticals, Inc. - Port Washington, NY
- AA. Hikma Americas, Inc. - Memphis, TN
- BB. Imprimis NJOF, LLC – Ledgewood, NJ
- CC. Integra LifeSciences Corporation – Cincinnati, OH
- DD. Integra York PA, Inc. – York, PA
- EE. Medline Industries Holdings, LP – Wilmer, TX
- FF. Neos Therapeutics Brands, LLC – Grand Prairie, TX
- GG. Nephron SC, Inc. - West Columbia, SC
- HH. Peyton's Phoenix – Phoenix, AZ
- II. Protein Sciences Corporation – Meriden, CT
- JJ. Pfizer Inc. - Pleasant Prairie, WI
- KK. Saol Therapeutics Inc. - Roswell, GA
- LL. Vanda Pharmaceuticals Inc. – Washington, DC
- MM. West-Ward Pharmaceuticals Corp. - Lockbourne, OH

Applications for Out-of-State Medical, Devices, Equipment and Gases – Non Appearance:

- NN. Complete Care Medical Supply Inc. – Encino, CA
- 00. Essential Medical Solutions, Inc. - Yorkville, TN
- PP. DePuy Synthes Products Inc. – Monument, CO
- QQ. Freedom Orthotics, Inc. - Dunedin, FL
- RR. HCS TENS Services LLC – Kansas City, MO
- SS. IMS Experts, LLC – Mansfield, TX
- Mari Medical Care LLC Powder Springs, GA TT.
- UU. National Bladder Association, LLC - Oviedo, FL
- VV. Sycamore Personal and Wellness Care, LLC – Dallas, TX
- WW. Walgreens Mail Service Tempe, AZ

Applications for Nevada Pharmacy – Non Appearance:

- XX. Elite Endoscopy Southwest – Las Vegas
- YY. Precision Surgery Center – Las Vegas

Tallie Pederson recused from participation on Items K, R and WW, due to her employment with Walgreens.

Board Action:

Motion: Kevin Desmond moved to approve the Consent Agenda with the exception of

Items K, R and WW.

Second: Robert Sullivan

Action: Passed unanimously

Board Action:

Motion: Jason Penrod moved to approve Consent Agenda Items K, R and WW.

Second: Robert Sullivan

Action: Passed unanimously

Tallie Pederson did not vote on this matter.

5. Discipline

A. Mostaqul Huq, R.Ph (16-041-RPH-N)
B. Walgreens #12488 (16-041-PH-N)

Tallie Pederson recused from participation in this matter due to her employment with Walgreens.

Mostaqui Huq and Tom Bui, Healthcare Supervisor for Walgreens, appeared and were sworn by President Basch prior to answering questions or offering testimony.

Bill Stilling was present as counsel representing Mr. Hug and Walgreens.

Mr. Edwards explained that in April 2016, patient W.R. presented a prescription for sixty (60) niacinamide 500 mg tablets with the instructions to take one tablet by mouth twice a day. The prescription was filled for niacin 500 mg tablets rather than the niacinamide 500 mg tablets as prescribed. Mr. Huq discovered that the niacinamide 500 mg tablets prescribed were not in stock and believed that niacin is the pharmacological equivalent of niacinamide and allowed the substitution. Mr. Huq did not contact the prescriber regarding the change.

Mr. Edwards explained that three Causes of Action are listed in the Accusation. He requested that the Second Cause of Action, regarding proper counseling, be dismissed because there is record that counseling did take place.

Mr. Edwards presented a Stipulation and Order regarding Mr. Huq and Walgreens Pharmacy #12488. Those Respondents admit that evidence exists to establish a basis for the violations alleged in the Accusation.

Mr. Huq shall pay a fine of \$500.00 and complete one additional CEU on the topic of Nevada Pharmacy Law.

Walgreens Pharmacy #12488 shall pay an administrative fee of \$495.00.

Mr. Huq and Mr. Stilling agreed to the Stipulation presented.

Board Action:

Motion: Jason Penrod moved to approve the Stipulation and Order as presented.

Second: Darla Zarley

Action: Passed unanimously

C. Lakshmi Sriharsha Bingi, R.Ph (16-069-RPH-N)
D. Safeway Pharmacy #2255 (16-069-PH-N)

Darla Zarley disclosed that Mr. Bingi was a former student, but stated that she would be able to participate in this matter fairly and without bias.

Lakshmi Bingi, Sherry Williams, pharmaceutical technician, and Jig Patel, District Manager for Safeway, appeared and were sworn by President Basch prior to answering questions or offering testimony.

Mr. Edwards moved to have Exhibits admitted into the record.

Mr. Bingi had no objections to the Exhibits

President Basch admitted the Exhibits into the record.

Mr. Edwards explained that in October 2016, A.C. filed a complaint with the Board Office on behalf of her sixteen year old daughter H.C. In the complaint, A.C. alleges that Mr. Bingi administered a flu vaccine to her daughter without parental consent. A.C. also indicated that her daughter is allergic to eggs and that she suffered an allergic reaction which she attributes to the administration of the flu vaccine.

Mr. Edwards called Mr. Bingi as a witness.

Mr. Bingi reviewed the Exhibits for the Board. He stated that the patient's mother A.C. called the pharmacy to inform him of the error. Mr. Bingi admitted to the charges in the Accusation and that he violated the pharmacy's protocol. Mr. Bingi apologized for not reviewing the patient's vaccine consent form more carefully.

Mr. Edwards called Ms. Williams as a witness.

Ms. Williams described her role as pharmaceutical technician to ask patients if they would like to receive a vaccination and to help the patient complete the appropriate vaccine consent form.

Mr. Edwards called Mr. Patel as a witness.

Mr. Patel described Safeway's response to Mr. Bingi's error. He admits that Mr. Bingi did violate Safeway's protocol, but explained that Mr. Bingi did cross reference the patient's allergies with her vaccination history on WeblZ.

Mr. Patel and Mr. Bingi answered questions to the Board's satisfaction regarding the changes to Safeway's policies and procedures and Mr. Bingi's practices.

Board Action:

Motion: Jason Penrod moved to find Lakshmi Sriharsha Bingi guilty of the First Cause

of Action.

Second: Darla Zarley

Action: Passed unanimously

Board Action:

Motion: Jason Penrod moved to find Safeway Pharmacy #2255 guilty of the Second

Cause of Action.

Second: Darla Zarley

Action: Pass unanimously

Mr. Edwards stated that Board Staff recommends Mr. Bingi pay a fine of \$1,000.00 and complete two additional CEU on the topic of safe immunization practices.

Board Action:

Motion: Jason Penrod moved to accept Board Staff's recommendation for penalty.

Second: Darla Zarley

Action: Passed unanimously

Mr. Edwards stated that Board Staff recommends Safeway pay an administrative fee of \$495.00 and shall provide Board Staff with Safeway's updated policies and procedures regarding immunizations. Safeway shall notify Board Staff once pharmacy staff has been retrained on the updated policies and procedures within thirty days.

Board Action:

<u>Motion:</u> Jason Penrod moved to accept Board Staff's recommendation for penalty.

Second: Darla Zarley

Action: Passed unanimously

6. Application for Pharmacist – Reciprocation – Appearance

Kenneth J. Pettengill

Kenneth Pettengill appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Pettengill stated that he is currently employed as a pharmacist for Wells Pharmacy Network in Florida. He added that he is applying for a Nevada Pharmacist License because his employer would like a pharmacist licensed in each state, and mentioned that Wells Pharmacy Network is working on expanding into the state in the future.

Mr. Pettengill explained that he indicated that he had past disciplinary actions and issues with law enforcement in other states.

The Board questioned Mr. Pettengill regarding his past DUI and drug charges.

Mr. Pettengill described his charges and arrests and stated that since then he has completed a two year drug court program, random drug tests, a five year PRN-PRN contract and a ninety-six hour assessment. He stated that after his completion of these programs and treatments both Georgia and Idaho approved his pharmacist license in their states.

The Board expressed concern regarding the wide time table that Mr. Pettengill's issues with law enforcement occurred. The Board questioned Mr. Pettengill regarding his current involvement in treatment and employment.

Mr. Pettengill stated that he is currently active in AA.

The Board offered Mr. Pettengill the option to table his application to be evaluated by PRN-PRN in Nevada.

The Board tabled Mr. Pettengill's application for Nevada Pharmacist at his request.

7. Application for Out-of-State Wholesaler – Appearance:

Dastech International Inc. - Great Neck, NY

Luz Cazenueve, facility manager, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Pinson explained that Dastech International Inc. was asked to appear to discuss their business practice and procedure specifically regarding red phosphorus, which can be used to make methamphetamine.

Ms. Cazenueve explained that Dastech International Inc. (Dastech) has been in business for 37 years and added that Dastech has worked with red phosphorus for about 20 years.

Ms. Cazenueve answered questions to the Board's satisfaction regarding Dastech's policies and procedures, customer screening and product tracking. Ms. Cazenueve explained that products are sold in full drum quantities and tracked down to the ounce.

Mr. Wuest stated that Board Staff has contacted DEA regarding this application and DEA expressed that they were comfortable with issuing Dastech an Out-of-State Wholesaler License.

Board discussion ensued regarding Dastech providing a copy of the qualifications for the buyer (DEA form 486) as well as a list of their customers in Nevada.

Board Action:

Motion: Tallie Pederson moved to approve Dastech International Inc.'s Application for

Out-of-State Wholesaler License. Dastech International shall provide to Board

Staff copies of their Nevada customer's DEA form 486.

Second: Jason Penrod

President Basch offered a friendly amendment to approve Dastech International Inc.'s Application for Out-of-State Wholesaler License pending a copy of their customer screening procedure and copies of the Nevada customer's DEA form 486. Dastech will provide the DEA form 486 for each customer until further notice.

Tallie Pederson and Jason Penrod accepted the friendly amendment.

Action: Passed unanimously

8. Requested Appearance:

James Wilson, MD – Nevada State Infectious Disease Forecast Station

Dr. Wilson stated that he is currently a pediatrician at the University of Nevada, Reno (UNR) with a background in global intelligence on health events.

Dr. Wilson discussed two intelligence systems. The first, is the Disease Activity Intelligence system, which gathers information from a variety of sources and can identify early triggers for an influenza season. He stated that pharmacists play a critical role in vaccination promotion and that this information would be useful for pharmacists.

Dr. Wilson also discussed the Antimicrobial Resistance Intelligence System, which is currently still in testing. He explained that the system gathers antibiogram data and creates antibiotic profiles to forecast antibiotic resistance.

Dr. Wilson welcomed the Board's participation in these systems and stressed the value in making this information available to prescribers and pharmacists.

The Board discussed how to circulate this information to pharmacists and asked Dr. Wilson to inform the Board and Board Staff once the Antimicrobial Resistance Intelligence System has successfully completed testing.

9. Application for Nevada Wholesaler – Appearance for Possible Action:

Lincare Inc. - North Las Vegas

No representative from Lincare Inc. was present.

- 10. Applications for Out-of-State Compounding Pharmacy Appearance:
 - A. Avella of Houston Houston, TX

Christopher Dinoffria, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Dinoffria explained that Avella of Houston is an outsourcing facility that provides sterile compounded products for hospitals.

Mr. Dinoffria answered questions to the Board's satisfaction regarding Avella of Houston's compounding procedure and prior FDA inspections. Mr. Dinoffria explained that Avella of Houston did have a recall due to a labelling issue, but stated that no recalls have occurred due to product integrity.

Board Action:

Motion: Kevin Desmond moved to approve Avella of Houston's Application for Out-of-

State Pharmacy License.

Second: Jason Penrod

Mr. Wuest stated that Board Staff has a 503B Outsourcing Facility Application that may be more appropriate based on the services Avella of Houston is offering.

Motion: Kevin Desmond moved to approve Avella of Houston's Application for 503B

Outsourcing Facility.

Second: Jason Penrod

Action: Passed unanimously

B. Enovex Pharmacy – Glendale, CA

No representative from Enovex Pharmacy was present.

11. Request to Add Compounding and Shipping of Sterile Compounded Drugs to an Existing Out-of-State Pharmacy License – Appearance:

Pinnacle Compounding – Missoula, MT

(PH03149)

This matter was rescheduled for the April 2017 board meeting at Pinnacle Compounding Pharmacy's request.

- 12. Applications for Nevada Pharmacy Appearance:
 - A. Dignity St. Rose Craig Ranch North Las Vegas

Tamarah Walker, Corporate Director of Pharmacy Services, Scott Weiss, Heather Grolet, managing pharmacist, and Laura Hennem, Market CEO, appeared and were sworn by President Basch prior to answering questions or offering testimony.

Mr. Weiss presented a letter of authorization allowing him to speak on behalf of the company.

Mr. Weiss stated that this is the first of four applications for community hospitals being built in the Las Vegas area.

Ms. Hennem described the layout of the facilities. She explained that the first floor will have 8 inpatient beds, 8 emergency department beds and 8 ER treatment bays. The second and third floors will house office space and other ancillary services.

Ms. Walker stated Dignity St. Rose uses a floor stock method and explained that Ms. Grolet will be the managing pharmacist and will be on-site to manage medications and load medications into the Omnicell. She explained that Ms. Grolet will be able to review orders both on-site and off-site.

Ms. Grolet answered questions to the Board's satisfaction regarding her education and work experience.

Ms. Walker, Mr. Weiss, Ms. Grolet and Ms. Hennem answered questions to the Board's satisfaction regarding the facility layout, compounding procedure, Omnicell locations and security.

Mr. Weiss described Dignity St. Rose's ownership structure. Board discussion ensued that physician ownership of a pharmacy must be less than 10%.

Board Action:

Motion: Jason Penrod moved to approve Dignity St. Rose's Application for Nevada

Pharmacy pending a positive inspection and documentation indicating that

physician ownership is less than 10%.

Second: Darla Zarley

Action: Passed unanimously

B. Nevada Health Rx – Las Vegas

Greg Sundem, President, Pamela Kalyan, managing pharmacist, Kimber Brooks, Secretary, and Noah Jussim, Counsel, appeared and were sworn by President Basch prior to answering questions or offering testimony.

Mr. Edwards provided background information regarding this application. He stated that the old pharmacy Meds Direct Rx had submitted an application for renewal on December 1, 2016. He stated that Board Staff discovered the pharmacy had been practicing unlicensed from the time period of October 31, 2016 until December 1, 2016. Board Staff sent a Cease & Desist notice along with a citation for \$1,000.00. Meds Direct Rx has since paid the fine and did not dispute the Cease & Desist. Mr. Edwards added that Ms. Kalyan was the managing pharmacist of Meds Direct Rx during the time period in questions.

The Board questioned Mr. Jussim and Ms. Kalyan on the activities that occurred at Meds Direct Rx during the time period of unlicensed activity.

Ms. Kalyan testified that Meds Direct Rx did not open during that time period, and the pharmacy had actually returned the medication in stock to their wholesaler.

Mr. Jussim explained that Nevada Health Rx is a separate entity and has no common ownership with Meds Direct Rx. He stated that Nevada Health Rx is a specialty retail pharmacy that currently has no plans to provide compounding services.

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

Board Action:

Motion: Kirk Wentworth moved to approve Nevada Health Rx's Application for Nevada

Pharmacy pending a positive inspection.

Second: Kevin Desmond

Action: Passed unanimously

13. General Counsel Report

VetSource Update

Mr. Edwards updated the Board on the status of the VetSource case. He stated that the Board and VetSource reached a settlement agreement. He explained that VetSource has dismissed their Federal Case and the Board has dismissed their State Case. He added that Board Staff and VetSource will work together to propose modifications to the Regulations to address VetSource's business model.

14. Approval of Pharmacy Practice Committee

Mr. Pinson presented a list of nine members to the Board. He explained that all members have been contacted and have agreed to be on the committee. He added that members were selected to be a well-rounded group with vast experience in the business of pharmacy.

Board Action:

Motion: Kevin Desmond moved to approve the Pharmacy Practice Committee members

as presented.

Second: Robert Sullivan

Action: Passed unanimously

15. Veterinary Dispensing Workgroup Formation

Mr. Wuest explained that the formation of this workgroup is in response to the Attorney General Opinion regarding licensing veterinarian dispensing. He stated that Board Staff has met with members of the industry, the Nevada State Board of Veterinary Medical Examiners and the Nevada Veterinary Medical Association to discuss this topic.

The goal of the workgroup is to discuss the current law or discuss possible modifications to the law regarding veterinarian dispensing.

Mr. Wuest stated that Jason Penrod and Kevin Desmond agreed to serve on the committee.

Jennifer Pedigo, Executive Director for Nevada State Board of Veterinary Medical Examiners, stated that David Pelsu and Ron Sandoval, veterinarians, have agreed to serve on the committee.

Board Action:

Motion: Kirk Wentworth moved to approve Kevin Desmond and Jason Penrod to serve

on the Veterinary Dispensing Workgroup.

Second: Tallie Pederson

Action: Passed unanimously

16. Executive Secretary Report:

A. Financial Report

Mr. Pinson presented the financial report to the Board's satisfaction.

B. Temporary Licenses

One temporary license was issued since the last meeting.

- C. Staff Activities:
 - a. DO Annual Meeting

Mr. Edwards' and Ms. Long's presentation to this group was well received.

- b. Speaking Engagements:
 - 1. Behavioral Health

Dave Jones presented on Ethics in Reno and Las Vegas. Both presentations were well received.

- 2. NABP Task Force on Law Enforcement
- D. Reports to Board
 - a. NABP Travel Grant

Mr. Pinson explained that Jason Penrod would be the Delegate for the Annual NABP Meeting and Darla Zarley would be the alternate. Mr. Pinson congratulated Mr. Penrod on receiving the NABP Travel Grant.

- E. Board Related News:
 - a. Opiate Research

Mr. Pinson presented an article for the Board's information. The article discussed opiate research on a new drug that does not interfere with breathing and appears to sidestep the brain's dopamine driven addiction circuitry.

- F. Activities Report
- 17. <u>Proposed Regulation Amendment Workshop</u> The purpose of the workshop is to solicit comments from interested persons on the following general topics that may be addressed in the proposed regulations.

Amendment of Nevada Administrative Code NAC 453.460 Partial **filling of prescription**. The proposed amendment would add Schedule II to the partial refill regulations.

Mr. Pinson stated that the proposed amendments would bring State Law into line with Federal Law regarding partial filling of Schedule II prescriptions.

Mr. Edwards explained that the proposed amendment would remove the seventy-two (72) hour restriction on partial fills for Schedule II prescriptions and instead would allow a partial fill for up to thirty days from the prescriptions written date.

President Basch opened the Public Comment.

There was no public comment.

At Ms. Pederson's request, Board Staff clarified the language regarding the prescription written date.

Board Action:

Motion: Kevin Desmond moved to adopt the proposed amendments to NAC 453.460

and move forward to Public Hearing.

Second: Kirk Wentworth

Action: Passed unanimously

18. Date and Location of Next Scheduled Board Meeting:

April 12-13, 2017 – Las Vegas

19. Public Comment March 1, 2017 5:00 PM

Liz MacMenamin, RAN, informed the Board that the Prescription Drug Round Up will take place on April 29, 2017. Ms. MacMenamin asked for pharmacists and pharmaceutical technicians to volunteer at one of the locations.