



Nevada State Board of Pharmacy

431 W. PLUMB LANE • RENO, NEVADA 89509
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
E-mail: pharmacy@pharmacy.nv.gov • Website: bop.nv.gov

BOARD MEETING

Airport Plaza Hotel
1981 Terminal Way
Reno

March 2 and 3, 2011

The meeting was called to order at 9:00 a.m. by Beth Foster, Board President.

Board Members Present:

| | | |
|------------------|-------------|----------------|
| Keith Macdonald | Beth Foster | Kirk Wentworth |
| Russell Smith | Jody Lewis | Kam Gandhi |
| Cheryl Blomstrom | | |

Board Members Absent:

Board Staff Present:

| | | | |
|--------------|-------------|----------------|---------------|
| Larry Pinson | Jeri Walter | Carolyn Cramer | Keith Marcher |
|--------------|-------------|----------------|---------------|

CONSENT AGENDA

1. Approval of January 11-12, 2011, Minutes
2. Applications for Out-of-State MDEG – Non Appearance:
 - A. American HomePatient, Inc. – Nashville, TN
 - B. Astra Tech Inc. – Waltham, MA
 - C. CPAP Care Club LLC – Franklin, TN
 - D. Hanger Prosthetics & Orthotics West, Inc. – Phoenix, AZ
 - E. Medtronic Heart Valve – Santa Ana, CA
 - F. Medtronic USA, Inc. – Fort Worth, TX
 - G. Medtronic USA, Inc. – Louisville, CO
 - H. Monitor Medical Inc. – Stafford, TX
 - I. Park Street Health Services, LLC – Miami, FL
 - J. RGH Enterprises, Inc. – Rancho Cucamonga, CA
 - K. Smart Remedies – California City, CA
 - L. Symbius Medical, LLC – Sandy, UT
 - M. Total Mobility & Modification Services – Sanford, IL

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

- N. Advanced Infusion Solutions – Clinton, MS
- O. All in One Pharmacy, Inc. – Harbor City, CA
- P. DCI Pharmacy-Kansas City – Kansas City, MO
- Q. General Home Pharmacy – Westlake Village, CA
- R. MyVetDirect.com – Sandston, VA
- S. Vets First Choice – Gretna, LA

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

- T. ABO Pharmaceuticals – San Diego, CA
- U. Allied Medical Supply, Inc. – Weaverville, NC
- V. Amgen USA, Inc. – Juncos, PR
- W. A.R. Medicom Inc. – Augusta, GA
- X. Benco Dental Supply Co. – Fort Wayne, IN
- Y. Benco Dental Supply Co. – Pittston, PA
- Z. Covidian – Ontario, CA
- AA. Diplomat Specialty Pharmacy – Flint, MI
- BB. Edwards Lifesciences, LLC – Irvine, CA
- CC. Edwards Lifesciences Technology SARL, LLC – Anasco, PR
- DD. Heel Inc. – Albuquerque, NM
- EE. Owens & Minor Healthcare Logistics – Redlands, CA
- FF. Prodigy Health Supplier Corporation – Austin, TX
- GG. Tyco Healthcare Group LP – Atlanta, GA
- HH. Tyco Healthcare Group LP – Chicopee, MA

- II. Tyco Healthcare Group LP – Crystal Lake, IL
- JJ. Tyco Healthcare Group LP – Wabasha, MN
- KK. Vet Brands International, Inc. – Miramar, FL

Application for Nevada Pharmacy – Non Appearance

- LL. Boulder City Outpatient Surgery Center – Boulder City

Discussion:

The consent agenda applications and supporting documents were reviewed.

Board Action:

Motion: Russ Smith found the consent agenda application information to be accurate and complete and moved for approval.

Second: Kam Gandhi

Action: Passed Unanimously.

Motion: Kirk Wentworth found the minutes accurate and complete and moved for approval.

Second: Kam Gandhi

Action: Passed Unanimously.

REGULAR AGENDA

3. Disciplinary Actions:

- A. Robert Culliver, R.Ph (10-074-RPH-N)
- B. CVS/pharmacy #9168 (10-074-PH-N)

NOTE: Jody Lewis recused from participation in this matter as she is an employee of CVS.

Mike Dyer was present to represent CVS and Mr. Culliver represented himself.

Carolyn Cramer presented a settlement agreement for the Board's consideration. The details include that Mr. Culliver will plead guilty to the First Cause of Action and CVS will pay a fine of \$1,000.00 on his behalf. For the Second Cause of Action, CVS will work to correct its computer inadequacy and report the results to Board staff. There is no contest from CVS on the Third Cause of Action in owning and operating the pharmacy in which the error in this matter was made.

Mr. Dyer described the procedures CVS requires in their pharmacies and he noted that pharmacy staff did not follow the policies and procedures. CVS will augment their policies and procedures, re-educate pharmacy staff and have them read and initial that they have read and understand the procedures to ensure they are knowledgeable in the standards CVS will implement.

Keith Marcher advised the Board that they could accept or reject the settlement agreement. If they reject the agreement then the parties will begin the hearing process. If they chose to accept the agreement then they need to make a motion.

Board Action:

Motion: Cheryl Blomstrom moved to accept the settlement agreement as presented.

Second: Kam Gandhi

Action: Passed Unanimously

Carolyn Cramer noted for the record that Alayna Helleson had been noticed appropriately, however was not present. Ms. Cramer continued and called Scott Smith to testify.

Scott Smith, detective for the Reno Police Department, appeared and was sworn by President Foster prior to answering questions or offering testimony.

Mr. Smith testified that an undercover agent had purchased Norco for \$60.00 from Alayna Helleson. Another buy was arranged but was not effectuated. Officers from the Reno Police Department went to Ms. Helleson's home where Ms. Helleson gave them permission to search her residence. Mr. Smith testified that officers found thirteen different types of drugs in various locations of her home. Officers also questioned Ms. Helleson's boyfriend separately from Ms. Helleson and he showed the officers where drugs were located in her home.

Ms. Cramer presented the Reno Police Department arrest report, which was marked Exhibit 1, and was accepted into the record.

David Vasenden, owner of Don's Pharmacy, appeared and was sworn by President Foster prior to answering questions or offering testimony.

Mr. Vasenden testified that Ms. Helleson worked for him and was terminated from employment just prior to Ms. Helleson's arrest. Police officers advised him of her arrest for selling drugs to an undercover agent. Mr. Vasenden indicated that he began to notice controlled substance losses from the pharmacy and was investigating but could not determine how or who was taking the drugs. Ultimately he found that Ms. Helleson was stealing the drugs by putting them in the garbage and taking them out of the pharmacy in that manner. Mr. Vasenden estimated his loss of approximately \$15,000.00 worth of drugs.

Board Action:

Motion: Kam Gandhi moved to find Alayna Helleson guilty of the alleged violations.

Second: Russ Smith

Action: Passed Unanimously

Motion: Kam Gandhi moved to revoke Alayna Helleson's pharmaceutical technician registration.

Second: Russ Smith

Action: Passed Unanimously

| | | |
|----|--------------------------|-----------------|
| D. | Stephanie Ingrey, R.Ph | (10-063A-RPH-N) |
| E. | Thomas Traynor, R.Ph | (10-063B-RPH-N) |
| F. | Raley's Drug Center #109 | (10-063-PH-N) |

Bill Stilling was present to represent Ms. Ingrey and Mr. Traynor. Ray Gates was present to represent Raley's Drug Center #109.

Carolyn Cramer presented a settlement agreement to the Board for their consideration. Ms. Ingry will plead guilty to the First Cause of Action and pay a fine of \$1,000.00 for the alleged violation. Mr. Traynor will plead guilty to the Second Cause of Action and participate in the Your Success Rx program for the alleged violation. Raley's Drug Center #109 will plead guilty to the Third Cause of Action and pay a fine of \$1,000.00 for owning and operating the pharmacy in which the alleged violations occurred.

Mr. Stilling and Mr. Gates agreed that Ms. Cramer accurately represented the settlement agreement.

Board Action:

Motion: Kirk Wentworth moved to accept the settlement agreement as presented.

Second: Cheryl Blomstrom

Action: Passed Unanimously

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

PGxHealth, LLC – New Haven, CT

Deanna Patton appeared and was sworn by President Foster prior to answering questions or offering testimony.

Ms. Patton explained that they do outsourcing of drugs however the Nevada Board of Pharmacy does not have a category for this type of process so they have applied as an out of state wholesaler. PGxHealth does not have drugs and they do not have a physical hands on process – it is all a virtual process from computer to computer. Ms. Patton explained the details of the process to the Board's satisfaction.

Board Action:

Motion: Keith Macdonald moved to approve the out of state wholesaler application for PGxHealth.

Second: Russ Smith

Action: Passed Unanimously

5. Applications for Nevada Pharmacy – Appearance:

A. Guided Alliance Pharmacy, Inc. – Reno

Tim McFadden appeared and was sworn by President Foster prior to answering questions or offering testimony.

Mr. McFadden advised the Board that they provide one patient in Nevada hemophilia products. The patient's insurance provider, Magellan, will not provide payment for the medication unless the patient's pharmacy is physically located in Nevada. Thus, the application, so he can provide the Nevada patient with health care.

Board Action:

Motion: Kam Gandhi moved to approve the application for Nevada pharmacy for Guided Alliance Pharmacy.

Second: Russ Smith

Action: Passed Unanimously

B. Precision Specialty Pharmacy – Las Vegas

Kelly Green, the managing pharmacist, Eugene Roseman, shareholder, and Mary Grear, pharmacist consultant, appeared and were sworn by President Foster prior to answering questions or offering testimony.

Mr. Green explained that he is a 22 year pharmacist that worked as a pharmacist in the military and 13 years at Merck Medco. Precision Specialty is a compounding pharmacy and he described the products they plan to compound.

Mr. Roseman is a shareholder and stated that he owns the building that they intend to use for the pharmacy. The Board questioned Mr. Roseman about Igor Tsyboulski's participation in Precision Specialty Pharmacy. Mr. Roseman indicated that Mr. Tsyboulski is an investor and chose to help fund this endeavor. Mr. Roseman was asked about his brother, Michael's, malpractice issue. Mr. Roseman indicated that he thought it was an insurance company issue where billing was being done under his wife's name rather than his own. Mr. Roseman assured the Board that patients were being seen and it was an insurance issue.

Board Action:

Motion: Keith Macdonald moved to approve the application for Nevada pharmacy for Precision Specialty Pharmacy.

Second: Jody Lewis

Action: Passed Unanimously

6. Application for Out-of-State Pharmacy – Appearance:

Home Care Services, Inc. – Metuchen, NJ

Mike Rigas, chief clinical pharmacist, appeared and was sworn by President Foster prior to answering questions or offering testimony.

Mr. Rigas described the business model of Home Care Services and their shipping procedures. They will ship into Nevada from New Jersey and they have almost completed the licensing process in California. They are ACHA accredited and they maintain a JACHO approved clean room. Mr. Rigas indicated that they ship the IVIG products directly to the patient which are then administered by a home care agent.

Board Action:

Motion: Kam Gandhi moved to approve the application for out of state pharmacy to Home Care Services.

Second: Keith Macdonald

Action: Passed Unanimously

7. Application for Nevada Wholesaler – Appearance:

Pacific Medical Prosthetics and Orthotics – Reno

Mark Weaver appeared and was sworn by President Foster prior to answering questions or offering testimony.

It was determined that the wrong application was submitted and the application was tabled until Board staff receives the appropriate paperwork.

8. Applications for Nevada MDEG – Appearance:

A. KCI USA, Inc. – Las Vegas

B. KCI USA, Inc. – Sparks

Harry Boniface appeared and was sworn by President Foster prior to answering questions or offering testimony.

Mr. Boniface described the KCI USA business model and answered questions from the Board to their satisfaction.

Board Action:

Motion: Kam Gandhi moved to accept both Nevada MDEG provider applications for KCI USA.

Second: Cheryl Blomstrom

Action: Passed Unanimously

C. Orthopedic Motion, Inc. – Las Vegas

Brittany Stryker appeared and was sworn by President Foster prior to answering questions or offering testimony.

Ms. Stryker described the Orthopedic Motion business model and answered questions from the Board to their satisfaction.

Board Action:

Motion: Kam Gandhi moved to accept the Nevada MDEG provider application for Orthopedic Motion.

Second: Kirk Wentworth

Action: Passed Unanimously

9. Application for Practitioner Dispensing – Appearance:

Ryan E. Mitchell, DO

Ryan Mitchell and Larry Espadero, PRN-PRN monitor, appeared and were sworn by President Foster prior to answering questions or offering testimony.

Dr. Mitchell was invited to appear before the Board to explain the circumstances of his answering all of the questions on the application for a dispensing license in the affirmative.

Dr. Mitchell explained that he was an impaired physician because of alcohol and substance abuse but he has been sober for two years. Dr. Mitchell advised that he has been in Mr. Espadero's group for almost two years and is in compliance with his

contract. He reviewed the reasons for his arrest in Nevada and indicated that the Michigan Board of Osteopathic Medicine paralleled the action taken by Nevada. Dr. Mitchell discussed the type of dispensing practice he would like to open and planned to dispense age management products, Latisse and other non-narcotic products.

Larry Espadero reported that Dr. Mitchell has accepted responsibility for his recovery and he has consistently produced negative UA's. Mr. Espadero indicated that he has spoken with Dr. Mitchell's previous monitor and they both feel comfortable with his progress. He also indicated that Dr. Mitchell had his family's support in his recovery process.

Board Action:

Motion: Kam Gandhi moved to approve the application for dispensing practitioner for Dr. Mitchell and would like him to report back to the Board upon completion of the PRN-PRN program.

Second: Russ Smith

Action: Passed Unanimously

10. Request for Pharmaceutical Technician in Training License – Appearance:

Andrea K. Boucher

NOTE: Keith Macdonald recused from participation as he is an employee of Wal-Mart.

Andrea Boucher appeared and was sworn by President Foster prior to answering questions or offering testimony.

Ms. Boucher advised the Board that there was a misunderstanding with Wal-Mart and she will have a job in the Carson City South Wal-Mart pharmacy. She informed the Board that she was a heroin addict and that she goes to a methadone clinic to maintain her sobriety. Ms. Boucher has a counselor at the clinic where goals are set and attained on a monthly basis. She indicated that she is drug tested regularly and she has been successfully titrating down on her methadone doses. Ms. Boucher indicated that she should complete her program at the methadone clinic in approximately one year at the rate she is decreasing her methadone dosage. Ms. Boucher stated that she had serious issues in her life that led her to begin using heroin, but she was doing well now.

The Board tabled Ms. Boucher's request for a pharmaceutical technician in training application until she is evaluated by PRN-PRN. Ms. Boucher was also asked to provide documentation from the methadone clinic verifying her progress.

11. Your Success Rx Presentation:

Katie Johnson, R.Ph

Katie Johnson gave a presentation for the benefit of the new Board members to enlighten them on the Your Success Rx program.

12. Request for Waiver:

Al Carter – Walgreens

Mr. Carter cancelled his request for an appearance.

13. Report on Texas Board of Pharmacy Meeting – Appearance:

Jiansheng Li, R.Ph

Hal Taylor and Jiansheng (Jason) Li appeared to report on the Texas Board of Pharmacy disciplinary procedures. Mr. Taylor explained the Texas model, allowing that they do not have disciplinary hearings in a public forum. Mr. Li advised that he attended one of the Texas meetings and they addressed licensing issues, thieving technician problems, and the Board president gave an overview of discipline. Mr. Li advised the Board that he feels he is a more responsible pharmacist now and has used this circumstance as a learning experience.

14. NABP Annual Meeting:

Elect Delegates

Board Action:

Motion: Kirk Wentworth moved to elect Russ Smith as the Delegate for the NABP Annual Meeting and himself for the Alternate.

Second: Kam Gandhi

Action: Passed Unanimously

15. General Counsel Report:

Legislative Update

Carolyn Cramer reported that the Nevada Board of Pharmacy has been asked to review several bill draft requests to provide fiscal impact statements to the legislature. Ms. Cramer also reported that she testified in support of SB 114, the bill that was forwarded to the Legislative Committee on Health Care from the Interim Study Group that was

formed by AB 326 to address prescription drug abuse in Nevada. Larry Pinson also testified before the Committee in support of SB 37.

16. Executive Secretary Report:

A. Financial Report

1. Treasurer's Report

Larry Pinson gave the financial report to the Board's satisfaction. Keith Macdonald detailed his meeting with Board staff regarding his inspection of the financial records.

B. Temporary Licenses

There were no temporary licenses issued since the last Board meeting.

C. Staff Activities

1. CPhA Meeting (2/13)

Mr. Pinson advised the Board that he spoke at the CPhA meeting in Palm Springs regarding our Inspecting for Safety practices. While attending that meeting, he was invited to speak in Montreal, however he was unable to accept that invitation due to scheduling conflicts.

D. Reports to Board

1. Letter to Tech Schools

Mr. Pinson noted that he sent a letter to the pharmaceutical technician schools addressing the issue of qualifying students before accepting them into their programs. He suggested that the students apply for technician in training registrations with the Board of Pharmacy prior to enrollment to ensure they meet the requirements. Mr. Pinson advised that the suggestion was well received.

E. Board Related News

Larry Pinson noted that he sent a letter to Governor Sandoval requesting approval to move forward with the Public Hearing since he had issued an Executive Order establishing a freeze on proposed regulations. Mr. Pinson believed that the regulations under consideration would qualify for the exemption detailed in the Executive Order because they affect public health and safety as well as being necessary to comply with federal law. We did get verbal approval to conduct the Public Hearing from the Governor's office.

The Board was provided with Fred Hillerby's report on legislative activities.

Mr. Pinson advised the Board that he hired Ken Scheubert to fill the investigator vacancy in the Las Vegas office caused by Fred Ackermann's retirement. He also indicated that he asked Ray Seidlinger to manage the office and that he enthusiastically accepted the assignment.

Russ Smith reported that he, Cheryl Blomstrom and Keith Macdonald visited the Task Force. He commended Joanee Quirk, Lisa Adams and Jenine Davis for their presentation to enlighten them about the purpose and function of the Task Force. They feel it is a good program and pleased that it is not law enforcement driven.

President Foster reported that she had the opportunity to meet with Governor Sandoval at the VA Hospital Pharmacy. She indicated that he was very supportive of their work and future plans for growth for the hospital and pharmacy. Governor Sandoval also praised Larry Pinson and the Board for their continuing work to ensure public safety.

F. Activities Report

17. Discussion and Determination – Appearance:

Chris Ferrari – Representing Consumer Healthcare Products Association
NPLEx Tracking Systems Presentation and Support for System

Mr. Ferrari appeared and noted that he was not in favor of scheduling pseudoephedrine as proposed in a BDR that is currently being presented by Senator Sheila Leslie during this legislative session. He indicated it would impact pharmacy staff and make it inconvenient and costly for the public to have to see their physician to get a prescription if they get a cold. Mr. Ferrari indicated that he represents the Consumer Healthcare Products Association (CHPA) and he is promoting the National Precursor Log Exchange (NPLEx) Tracking System. He stated that it is a multi-state e-tracking system that has been implemented by ten states nationwide and is supported by law enforcement. Mr. Ferrari described how the system worked to stop smerfers from obtaining large quantities of products necessary to make methamphetamine.

Mr. Pinson advised Mr. Ferrari that the Board had agreed to support Senator Leslie's bill draft to schedule pseudoephedrine at the January Board meeting. After discussion, the following motion was made.

Board Action:

Motion: Keith Macdonald moved to support any effective mechanism, such as the prescription monitoring program or NEPLEx, to control illegal sales of pseudoephedrine in Nevada.

Second: Cheryl Blomstrom

Action: Passed Unanimously

PUBLIC HEARING

18. Notice of Intent to Act Upon a Regulation:

1. **Amendment of Nevada Administrative Code 453.510 Schedule I**
Because of abuse of un-regulated products containing synthetic cannabinoids being sold in head shops, law enforcement has requested that the Board of Pharmacy schedule JWH-018, JWH-073, JWH-200, CP-47,497 5 and cannabicyclohexanol 5 in Schedule 1.

President Foster opened the Public Hearing.

Diane Machen, Washoe County Sheriff's Forensic Science Department, appeared and was sworn by President Foster prior to answering questions or offering testimony.

Ms. Machen expressed support for adopting this amendment and indicated that there will be additional compounds arise that will require scheduling as time goes on. Ms. Machen brought additional examples of purchases she had made from head shops in town that contain the products being considered for adoption today. She also indicated they are seeing more abuse in Washoe County.

President Foster closed the Public Hearing and asked for a motion.

Board Action:

Motion: Cheryl Blomstrom moved to adopt this regulation amendment as presented.

Second: Keith Macdonald

Action: Passed Unanimously

2. **Amendment of Nevada Administrative Code 453.520 Schedule II** Law enforcement has requested that the Board of Pharmacy add tapentadol and lisdexamphetamine to Schedule II.

President Foster opened the Public Hearing.

There was no public comment.

President Foster closed the Public Hearing and asked for a motion.

Board Action:

Motion: Kam Gandhi moved to adopt this regulation amendment as presented.

Second: Cheryl Blomstrom

Action: Passed Unanimously

3. **Amendment of Nevada Administrative Code 453.540 Schedule IV** This amendment will correct the spelling of Sibutramine.

President Foster opened the Public Hearing.

There was no public comment.

President Foster closed the Public Hearing and asked for a motion.

Board Action:

Motion: Russ Smith moved to adopt this regulation amendment as presented.

Second: Jody Lewis

Action: Passed Unanimously

4. **Amendment of Nevada Administrative Code 453.550 Schedule V** Law enforcement has requested the Board of Pharmacy to add Lacosamide to Schedule V.

President Foster opened the Public Hearing.

There was no public comment.

President Foster closed the Public Hearing and asked for a motion.

Board Action:

Motion: Keith Macdonald moved to adopt this regulation amendment as presented.

Second: Kirk Wentworth

Action: Passed Unanimously

5. **Amendment of Nevada Administrative Code 639.7105 Electronic Prescribing** This language will provide that the requirements of certain federal regulations must be satisfied before a prescription is transmitted electronically.

President Foster opened the Public Hearing.

There was no public comment.

President Foster closed the Public Hearing and asked for a motion.

The Board discussed the pros and cons of electronic prescribing. Mr. Pinson noted that the DEA was very close to approving at least one of the two agencies that would be authorized to transmit prescriptions electronically. If the prescription being electronically prescribed by the practitioner is through one of the DEA authorized agents the prescription is good.

Board Action:

Motion: Keith Macdonald moved to adopt this regulation amendment as presented.

Second: Cheryl Blomstrom

Action: Passed Unanimously

19. Next Board Meeting:

April 13-14, 2011 – Las Vegas

20. Public Comments and Discussion of and Deliberation Upon Those Comments

Liz Macmenamin came to the table to request that the Board prepare an emergency regulation with reference to the Wal-Mart v. Sanchez matter that has been brought to the Board's attention numerous times. President Foster noted that when Ms. Macmenamin and Mr. Amodei appeared at the December 2010 Board meeting it was determined that Board staff would work with interested parties by forming a committee and to meet with Brenda Erdoes at the Legislative Counsel Bureau. Larry Pinson formed a committee of Liz Macmenamin, Mark Amodei, Cheryl Blomstrom, Fred Hillerby and Beth Foster. First and foremost, Carolyn Cramer and Mark Amodei will meet with Brenda Erdoes and after that meeting a committee meeting will be called to discuss the findings. To date, Mark Amodei has not contacted Carolyn Cramer to affect a meeting with Brenda Erdoes.

Robert Long appeared and asked the Board when they planned to begin working on updating the hospital regs. He stated that he was asked to be on a committee to begin the process, however he had not heard when that process was slated to begin. Mr. Long was advised that the committee had not met as yet, and that the Governor has put a freeze on all regulations until 2012. Mr. Long also asked about the Telepharmacy regulations and he was advised that they had been adopted and that we would provide him with a copy of them.

Keith Macdonald directed Board staff to include a Discussion and Determination item on the agenda for the April Board meeting regarding disciplinary procedures.

Blank