

BOARD MEETING

at

Airport Plaza Hotel
1981 Terminal Way
Reno, Nevada

Wednesday, April 18, 2007

Thursday, April 19, 2007

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

Board Members Present:

Dave Wuest
Leo Basch
Ray Seidlinger

Keith Macdonald
Katie Craven

Barry Boudreaux
Ann Peterson

Board Members Absent:

Keith Macdonald absent April 19, 2007

Board Staff Present:

Larry Pinson

Jeri Walter

Louis Ling

Keith Marcher

CONSENT AGENDA

1. Approval of February 22-23, 2007, Minutes
2. Applications for Out-of-State MDEG – Non Appearance:
 - A. Capstone Orthopedic, Inc. – Castro Valley, CA
 - B. Cochlear Americas – Centennial, CO
 - C. Cypress Medical Products LLC – Libertyville, IL
 - D. Cypress Medical Products LLC – McHenry, IL
 - E. Express Medical Supply – Chula Vista, CA
 - F. Mobility Products Unlimited, LLC – South Daytona, FL
 - G. N2Sleep Homecare – Antioch, CA
 - H. Tactile Systems Technology Inc. – Minneapolis, MN

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

- I. Access Therapeutics, Inc. – Hawthorne, NY
- J. Famacia Estrella – Oxnard, CA
- K. Medical Arts Pharmacy Services, Inc. – Coral Springs, FL
- L. Med Specialties Compounding Pharmacy – Yorba Linda, CA
- M. Prime Therapeutics LLC – Albuquerque, NM
- N. PX Drugstore – North Hollywood, CA
- O. University of Utah Huntsman Cancer Pharmacy – Salt Lake City, UT
- P. University of Utah Moran Pharmacy – Salt Lake City, UT

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

- Q. McKesson Packaging Services – Concord, NC
- R. Merck & Co., Inc. – Duluth, GA
- S. Meridian Medical Technologies #1 – St Louis, MO
- T. Meridian Medical Technologies #2 – St Louis, MO
- U. Novis Pharmaceuticals, LLC – Plymouth Meeting, PA
- V. SkyePharma, Inc. – San Diego, CA

Application for Nevada Pharmacy – Non Appearance:

- A. Walgreens #09864 – Gardnerville

Discussion:

The consent agenda applications and supporting documents were reviewed.

NOTE: Leo Basch recused from participation in item 2W as he is employed by Walgreens.

Board Action:

Motion: Keith Macdonald moved to approve the February minutes as presented.

Second: Ann Peterson

Action: Passed Unanimously

Board Action:

Motion: Katie Craven read the information related to the consent items and found the information to be accurate and complete and moved for approval of item 2 excluding item 2W.

Second: Leo Basch

Action: Passed Unanimously

Motion: Keith Macdonald moved to approve item 2W.

Second: Katie Craven

Action: Passed Unanimously

After discussion of item 2L, the following action was taken.

Board Action:

Motion: Katie Craven moved to approve item 2L.

Second: Ray Seidlinger

Action: Passed Unanimously

REGULAR AGENDA

3. Applications for Nevada Pharmacy – Appearance:

A. Advanced Pharmacy Staffing Inc. – Las Vegas

Jerry Igbinovia appeared and advised the Board that he finally understands what he needs to do to open his business. He described that he has a facility and drugs and everything required to open a pharmacy.

Board Action:

Motion: Leo Basch moved to approve Advanced Pharmacy Staffing’s request for pharmacy license pending inspection.

Second: Barry Boudreaux

Action: Passed With One Negative Vote

B. CNS Scrips, LLC – Las Vegas

Roderick Salvalton and Shanella Blas-Catacutan appeared and described that CNS Scrips will be servicing small group homes in Nevada. They reviewed their procedures and policies to the Board’s satisfaction.

Board Action:

Motion: Barry Boudreaux moved to accept the application for pharmacy for CNS pending inspection.

Second: Ann Peterson

Action: Passed Unanimously

C. Pharmix Center, LLC – Las Vegas

Daniel Gelber and Yael Reiss appeared and described their business. They basically are a compounding mail service that fills and ships prescriptions for doctors for specific patients and that the doctors then bill the patients for the medications. Board staff advised Mr. Gelber and Mr. Reiss that that business model is not legal in Nevada. If they fill prescriptions for patients they also need to bill them for the medication. Mr. Gelber was asked to put policies and procedures together and return to a future Board meeting and present a new business model.

Board Action:

Motion: Ann Peterson moved to table the application for pharmacy for Pharmix Center until the June Board meeting.

Second: Barry Boudreaux

Action: Passed Unanimously

4. Application for Nevada Wholesaler – Appearance:

Med-Health Pharmaceutical Products LLC – North Las Vegas

NOTE: Barry Boudreaux recused from participation in this matter as he employed Ms. Richards in the past.

Ann Richards appeared and presented a binder of information to the Board for reference regarding their business model, facility, security, inventory control, electronic pedigree, standard operating procedures and other information for the Board's review.

Larry Pinson advised that Board staff visited Ms. Richards in Las Vegas and was duly impressed with their facility and their wholesaler concept. Mr. Pinson explained that they will be purchasing drugs directly from the manufacturer and that Ms. Richards is completely supportive of pedigrees. She has potential clients and staff and is ready to put her concept into practice.

Board Action:

Motion: Leo Basch moved to approve the application for MedHealth pending inspection.

Second: Katie Craven

Action: Passed Unanimously

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

Biofusion – Torrance, CA

Scott Nagasawa appeared and advised the Board that he has been shipping into Nevada to one patient to ensure the patient did not interrupt their drug therapy when the patient moved to Nevada. Mr. Nagasawa stated that he was told by Board staff that he could ship if he had an application in process.

Board Action:

Motion: Katie Craven moved to approve the out-of-state pharmacy application for Biofusion.

Second: Leo Basch

Action: Passed Unanimously

6. Application for Canadian Pharmacy – Non Appearance:

CanTrustRx Inc. – Winnipeg, Manitoba

Larry Pinson advised the Board that CanTrustRx applied to the Governor's office to be added to their website as an authorized Canadian pharmacy. The Governor's office referred CanTrustRx to the Board of Pharmacy and they have applied for licensure.

Board Action:

Motion: Ann Peterson moved to approve the application for pharmacy from CanTrustRx pending inspection.

Second: Barry Boudreaux

Action: 2 Negative Votes 3 Votes to Approve and President Wuest Voted to Approve – Motion Passed

7. Disciplinary Action:

A. Rebecca S. Craghill, PT (06-057-PT-N)

Rebecca Craghill appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Ms. Craghill renewed her pharmaceutical technician's registration and answered in the negative to the question that asked, "Since your last renewal or recent licensure have you been charged, arrested, or convicted of a felony or misdemeanor in any state?"

On June 24, 2005 Reno Justice Court issued a felony hold warrant regarding Ms. Craghill, charging her with drawing and passing a series of checks within a 90 day period with intent to defraud.

On August 26, 2005, Ms. Craghill was arrested for DUI as a result of her backing her car into another car in a parking lot. As a result of the accident, Ms. Craghill was administered a field sobriety test, which she failed. At that time the felony warrant was also discovered and Ms. Craghill was arrested on the felony warrant. Ms. Craghill testified that she had resolved the Reno Justice Court matter pleading it down to a misdemeanor and by paying restitution for the bad checks. Ms. Craghill provided the Board with documents that showed that on November 7, 2005, she plead guilty to reckless driving, for which she was sentenced to DUI school, attendance at the Victim Impact Panel, and 24 hours of community service.

On July 10, 2006, the Washoe County District Attorney's Office filed a Criminal Complaint against Ms. Craghill, the result of a March 23, 2006 automobile accident in which Ms. Craghill rear-ended her car into another car on the Mount Rose Highway. An investigation at the scene of the accident showed that Ms. Craghill appeared to be under the influence of a substance, and the investigation also found pills in a plastic bag that were later identified to be Tramadol and Klonopin for which Ms. Craghill had no lawful prescription at the time. Subsequent testing of Ms. Craghill's blood confirmed that she had the drugs in her system at the time of the accident. At hearing, Ms. Craghill explained that she had lawful prescriptions for the two drugs and she produced a copy of a 2005 prescription for Klonopin. She testified that she tested positive because she had taken the drugs the night before the accident and claimed that she was not impaired at the time of the accident. Ms. Craghill advised the Board that she was unaware of the Criminal Complaint and was provided with a copy.

Ms. Craghill testified that she had no excuse for answering the question on her renewal application incorrectly and repeatedly stated that she should have been more forthright with the Board when she filed her renewal application.

Louis Ling recommended that the Board proceed with the First Cause of Action, dismiss the Second Cause of Action, and dismiss the Third Cause of Action without prejudice.

Board Action:

Motion: Leo Basch moved to dismiss the Second Cause of Action.

Second: Barry Boudreaux

Action: Passed Unanimously

Motion: Leo Basch moved to find Ms. Craghill guilty of the First Cause of Action.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Leo Basch moved to have Ms. Craghill pay fees and costs in this matter and be approved for renewal of her pharmaceutical technician registration.

Second: Keith Macdonald

Amend: Ann Peterson asked to amend the motion to require Ms. Craghill to attend the first day of the Board's meeting in September.

The amendment was accepted by the First and the Second.

Action: Passed Unanimously

Motion: Ray Seidlinger moved to dismiss the Third Cause of Action without prejudice.

Second: Leo Basch

Action: Passed Unanimously

B. Rebekah Keechler, R.Ph (07-013-RPH-N)

Rebekah Keechler appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Board staff received a notice of termination of employment from Scolari's district pharmacy manager, David Chan. Ms. Keechler was terminated for making and filling false prescriptions for controlled substances for herself. It was found that Ms. Keechler had been making false prescriptions for various controlled substances which she would then take home for her personal use and the personal use of her husband. Over a ten month period Ms. Keechler had removed approximately 12,000 dosage units of hydrocodone 10/325 for her and her husband's personal use. Ms. Keechler did not pay for any of the controlled substances she took for herself and her husband.

Ms. Keechler testified that she had made false prescriptions for hydrocodone 10/325 for herself and her husband. Ms. Keechler advised that she and her husband have painful medical conditions and that when she moved to Carson City her physician would not continue prescribing the hydrocodone that she had been taking for migraine headaches, so she began self-medicating. She and her husband are both addicted to hydrocodone and that at the height of her addiction she was taking approximately 50 dosage units of hydrocodone per day. Ms. Keechler explained that she had enrolled in the PRN-PRN program and that she and her husband were jointly attending NA meetings almost every day. When asked if she would feel comfortable working in a pharmacy at this time, Ms. Keechler stated that she would not.

Board Action:

Motion: Ann Peterson moved to find Ms. Keechler guilty of the First Cause of Action.

Second: Katie Craven

Action: Passed Unanimously

Motion: Ann Peterson moved for Ms. Keechler's pharmacist license to continue to be suspended, to continue in the PRN-PRN program, and make restitution to Scolari's before she requests reinstatement of her license. When she is ready to request reinstatement, Ms. Keechler needs to appear with a representative of PRN-PRN for a report on Ms. Keechler's progress with the program.

Second: Keith Macdonald and amended that Ms. Keechler's license be suspended at least until February, 2008.

Ms. Peterson accepted the amendment.

Action: Passed Unanimously

C. Noreen M. Fish, PT (07-007-PT-N)

NOTE: Leo Basch recused from participation as he is employed by Walgreens.

Louis Ling noted for the record that Ms. Fish was not present even though she had been noticed appropriately. Ms. Fish's Accusation was Unclaimed though the postal service had left her three notices before returning it to Board staff.

Board staff received notice of termination of employment of Ms. Fish because she had removed cash and 450 hydrocodone tablets from her employing Walgreen's pharmacy.

Board Action:

Motion: Keith Macdonald moved to find Ms. Fish guilty of the alleged violations.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Keith Macdonald moved to revoke Ms. Fish's pharmaceutical technician registration.

Second: Ann Peterson

Action: Passed Unanimously

D. Dana M. Dillon, PTT (07-014-PTT-N)

NOTE: Leo Basch recused from participation as he is employed by Walgreens.

Louis Ling noted for the record that Ms. Dillon was not present even though she had been noticed appropriately. Ms. Dillon's Accusation was returned. Ms. Dillon had moved and the forwarding on her mail had expired.

Board staff received notice of termination of employment of Ms. Dillon from Walgreens. Ms. Dillon appeared at work under the influence of alcohol. Ms. Dillon had a strong odor of alcohol on her breath and the odor of alcohol was even stronger when she returned from lunch. Ms. Dillon was tested and had a blood alcohol level of 0.08.

Board Action:

Motion: Ray Seidlinger moved to find Ms. Dillon guilty of the alleged violations.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Ray Seidlinger moved to revoke Ms. Dillon's pharmaceutical technician-in-training registration.

Second: Ann Peterson

Action: Passed Unanimously

E. AME Health Care (07-004-MP-N)

Marcia Giller appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Louis Ling gave a history of how the Board of Pharmacy came to license MDEG providers. He also advised that he would be presenting the testimony of Joe Depczynski to give an account of the conditions he found at AME Health Care.

Joe Depczynski, Board investigator/inspector, appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Mr. Depczynski described his job duties for the Board. Mr. Depczynski advised that he did an unannounced inspection of AME on January 31st, 2007. He noted that when he arrived at AME the facility was dirty. He described what he saw and took pictures while he was there.

Mr. Ling presented Exhibit 1 – pictures of AME. The Exhibit was accepted into the record.

Mr. Depczynski described each picture in Exhibit 1. In general, the pictures depicted the unkempt, dirty, unorganized facility.

Mr. Depczynski testified that he found no records for the concentrators that were covered in plastic with dirt and dust on the plastic. There was a note of maintenance in July, 2002, on one of the concentrators, but no indicator on any of the others.

Ms. Giller indicated that she had a log.

Mr. Depczynski asked for proof of liability insurance. AME had a bulleting board where licenses were posted, but there was no proof of liability insurance. Mr. Depczynski also noted that there was no evidence of a fire inspection. Mr. Depczynski was told the fire inspector was there about five years ago but did not give them a certificate. Mr. Depczynski advised that calibration of concentrators is supposed to be logged, but no log was produced. Mr. Depczynski also advised that the calibrator was not operable when he was inspecting AME on January 31st, 2007. Mr. Depczynski asked to see logs for expiration dates on oxygen tanks. Mr. Depczynski indicated that Ms. Giller produced a log where the last entry was July, 2006. He stated that he found no records of patients using their concentrators. Mr. Depczynski was told that they only had one patient. He asked to see the file on that patient and was given a small bundle of papers with no records of instruction or calibration records.

Mr. Depczynski saw a customer come in while he was there and he asked to see the record of what had just transpired. He stated he was given a copy of a handwritten receipt with no patient name or anything more than the amount of \$1,200.00 for purchase of something (not noted).

Mr. Ling presented Exhibit 2 – a letter from Jack Paige, previous Board inspector, to Ms. Giller dated July 11, 2002. The Exhibit was admitted into the record.

Mr. Ling presented Exhibit 3 – one page of notes from AME's 2003 inspection performed by Jack Paige. The Exhibit was admitted into the record.

Mr. Ling presented Exhibit 4 – 2004 Inspection Report for AME. The Exhibit was admitted into the record.

Mr. Ling presented Exhibit 5 – a packet of photos taken by Jack Paige of the interior of AME. The Exhibit was admitted into the record.

While performing his inspection, Mr. Depczynski asked about a motorized wheelchair that was partially disassembled. He was told they were waiting for parts. He asked if someone came in right now to buy a wheelchair what would they do. He was told that they would try to figure out how to put it back together with the parts they had.

Ms. Giller indicated that they have completely cleaned up the premises since Mr. Depczynski was there. In fact, when he arrived for the unannounced inspection, they were in the process of doing just that which is why it was in such disarray. Ms. Giller

had in her possession the proof of liability insurance and a completed log. They had insurance when Mr. Depczynski was there, but they did not have the certificate.

Ms. Giller presented Exhibit A – a faxed copy of AME’s insurance certificate that was faxed to AME on the day Mr. Depczynski was there. The Exhibit was admitted into the record.

Ms. Giller presented Exhibit B – a copy of AME’s insurance policy. The Exhibit was admitted into the record.

Ms. Giller answered many questions presented by the Board regarding the operation of AME.

Louis Ling gave closing statements and reviewed each Cause of Action.

First Cause of Action – Cleanliness of AME

Second Cause of Action – No proof of liability insurance

Third Cause of Action – No proof of fire certificate

Fourth Cause of Action – Failure to maintain log or record of repairs

Fifth Cause of Action – Failure to maintain a device to calibrate or test equipment

Sixth Cause of Action – Failing to keep records to track and recall all gasses dispensed

Seventh Cause of Action – Failure to give instructions to patients regarding set up, use and maintenance of equipment

Mr. Ling recommended revocation of AME’s MDEG license, however if the Board did not feel that was appropriate, probation with strict requirements for operation of their facility.

The Board discussed the pros and cons of the recommendation.

Board Action:

Motion: Leo Basch moved to dismiss the Second Cause of Action.

Second: Ray Seidlinger

Action: Passed With One Negative Vote

Motion: Leo Basch moved to find AME guilty of the First, Third, Fourth, Fifth and Sixth Causes of Action.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Leo Basch moved to dismiss the Seventh Cause of Action.

Second: No Second

Action: Motion Failed

Motion: Leo Basch moved to find AME guilty of the Seventh Cause of Action.

Second: Ann Peterson

Action: Passed With One Negative Vote

The final motion:

Motion: Leo Basch moved to put AME on probation for two years, unannounced inspections three times within the first six months and then every six months for the remaining 18 months of probation, execute a policy to require all employees to have knowledge of where all records are kept, and pay the fees and costs in this matter. AME's license will be suspended effective the day this Order is signed until AME becomes compliant with Nevada's MDEG laws.

Second: Katie Craven

Action: Passed Unanimously

8. Your Success Rx Report – Appearance:

Katie Johnson, R.Ph

Katie Johnson and Davidson Okpukpara appeared and gave Mr. Okpukpara's Your Success Rx report. Mr. Okpukpara explained his experience of Ms. Johnson's program. He found the experience of evaluating his pharmacy practice a valuable exercise. Mr. Okpukpara learned that the last chance you have to catch an error is while you are counseling. Now Mr. Okpukpara uses the show and tell method of counseling and finds it effective. Mr. Okpukpara noted that they have changed their filling procedures at the pharmacy he is now working in to include baskets. They have also implemented a break procedure and Mr. Okpukpara noted that even a half hour break helps his concentration. Mr. Okpukpara advised the Board that since experiencing the Your Success Rx program he no longer works long hours for days on end and feels he is doing a better job as a pharmacist.

9. CSTF Compliance Officer – Appearance:

Joanee Quirk

Ms. Quirk appeared and advised the Board that it does not look promising that she will receive grant funds to continue the intervention officer position in Las Vegas. The grant that is funding the intervention officer position ends in September and there has been no indication that a grant will be assigned for that purpose. Ms. Quirk indicated that she

has not assigned the intervention officer any new clients and the clients that he is working with now will have completed their program by September.

Board Action:

Motion: Keith Macdonald moved to terminate the current contract when the grant runs out.

Second: Leo Basch

Action: Passed Unanimously

10. Legislative Update:

Discussion and Determination of Board's Position Regarding Bills Involving Pharmacy and Drugs

SB98 – Abolish the Board. The bill has been gutted and the Board is still in business.

SB5 – Recycling Cancer Drugs. The latest version of this bill passed and we will be required to write regs and establish a reporting mechanism to report to the legislature on a quarterly basis. Liz Macmenamin noted that it is just the expensive cancer drugs and not CII's yet that may be an issue.

AB84 – Drug Expiration Dates. Ms. Macmenamin reported that that bill is dead and it will not go back to the manufacturer's expiration date.

AB235 – Indicate Use of Drug on Label. The language of this bill has been watered down to require use of drug on the label to "if the patient requests."

AB446 – Task Force. This will establish a requirement for a physician to check with the task force if the patient is new to the physician, is seeking narcotics, and raises suspicion with the physician. Hopefully this will be a standard of practice for the physician.

AB128 – Gifting. Reports will be monitored to ensure that gifting does not go over \$1,000.00 per physician.

SB231 – Wholesaler.

SB232 – Price Posting. Posting of drug prices will be posted by Health and Human Services on their website.

SB197 – Died.

Gerontology: There is a bill that would to make it mandatory for pharmacy students to take pharmaceutical gerontology courses in pharmacy school. Since there are no such courses taught in pharmacy school this bill would make it impossible to license any pharmacists. It has been revised to suggest that gerontology training be achieved through continuing education.

Homeopathy: The four homeopathy bills that were introduced were rolled into one that would require an interim study that would explore all of their issues. Of concern, these bills would allow homeopathic practitioners to prescribe allopathic medicine without an MD.

Methamphetamine: Pseudoephedrine is currently an over the counter product that the Board of Pharmacy does not regulate other than to ensure compliance with federal law requiring products containing pseudoephedrine to be behind the pharmacy counter. If legislation passes, reports will have to be produced from quick stop stores, such as 7-11, regarding their sales of these products. If 7-11's have to do this they probably will not sell products containing pseudoephedrine any more. The shift will be to herb shops, smoke shops, dollar stores, etc. This bill is expected to come out of the Assembly and move to the Senate.

11. Report and Recommendations from the CE Committee:

- A. Continuing Education Requests
 - 1. Geriatric Assessment, Treatment and Recovery in Disasters
 - 2. Certification Examination in Geriatric Pharmacy

Geriatric Assessment, Treatment and Recovery in Disasters was approved for 1.5 accredited continuing education units.

Sitting for the Certification Examination in Geriatric Pharmacy will not be granted CE credit since the credit is achievable for the course work leading up to that exam.

- B. Continuing Education Credit for "Your Success Rx" (non-mandated)

If the Your Success Rx program is not mandated by Board Order, 2.0 hours of continuing education per section was approved

- C. School Enrollment to Further Pharmacy Education as CE Credit

School Enrollment to Further Pharmacy Education was approved for 1.0 CE credit per unit of course work.

- D. Credit for CPR Courses

CPR courses were approved for 2.0 hours of continuing education.

Board Action:

Motion: Keith Macdonald moved to approve the continuing education hours as recommended by the CE Committee.

Second: Barry Boudreaux

Action: Passed Unanimously

12. General Counsel Report

There was no general counsel report.

13. Executive Secretary Report:

- A. Financial Report
- B. Investment Report

Mr. Pinson gave the financial and investment reports to the Board's satisfaction including a detailed breakdown of line items.

C. Temporary Licenses

There were three temporary licenses granted since the last Board meeting.

- D. NABP Considerations
 - 1. Resolutions
 - 2. Executive Committee Candidates
 - 3. Task Force Interest
 - 4. Portland

Mr. Pinson advised the Board that he, Louis Ling, and Keith Macdonald will be doing a presentation at the Annual Meeting in Portland regarding the Wholesaler issue.

E. Data Recovery Report

Larry Pinson reported that we did get our scanned documents back. Mr. Ling had filed an \$8,000.00 complaint with UPS for damages caused by not packing the computer drives so they were secure.

F. University of Utah Alcohol & Drug Abuse School

If anyone is interested in attending the University of Utah Alcohol and Drug Abuse School, Mr. Pinson has the brochure and application.

G. Staff Activities

- 1. Meetings

Mr. Pinson reported that he and Joe Depczynski did a 7:00 a.m. CE program in Fallon. He also spoke at the University of California at San Francisco and advised them of our licensing procedures. Mr. Pinson noted that the meeting with the Governor's office had been postponed.

- 2. Miscellaneous

It has come to Board staff's attention that out-of-state pharmacists are counseling patients in Nevada. They are reviewing patient's files and giving advise. The question arose – do they need to be licensed in Nevada to perform these tasks. Keith Marcher

advised the Board that the Nursing Board had addressed the same issue, but he could not remember what they determined. Board staff was directed to check with the Nursing Board to see how they handled this matter and bring it back as a Discussion and Determination item at the next Board meeting.

3. Activities Report

The Activities Report for the February 2007 Board meeting that was sent to Legislators was presented to the Board for their reference.

WORKSHOP

14. **Proposed Regulation Amendment Workshop** – 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.

1. **Amendment of NAC 453.460** Partial Filling of Controlled Substances in Schedules III, IV and V

There was no public comment.

Board Action:

Motion: Ray Seidlinger moved to proceed with this regulation amendment as presented.

Second: Leo Basch

Action: Passed Unanimously

2. **Amendment of NAC 453.530** Scheduling Human Growth Hormone as a Controlled Substance

There was no public comment.

Board Action:

Motion: Barry Boudreaux moved to proceed with this regulation amendment as presented.

Second: Ann Peterson

Action: Passed Unanimously

3. **Amendment of NAC 639.593** Wholesaler Changes Regarding Manufacturers and VAWD-Certified Wholesalers

This amendment will exempt wholesalers from stringent licensing requirements if they are VAWD certified.

There was no public comment.

Board Action:

Motion: Ray Seidlinger moved to proceed with this regulation amendment as presented.

Second: Ann Peterson

Action: Passed Unanimously

4. **Amendment of NAC 639.7425** Removing Education Requirements for Dispensing Technicians

Mary Staples, representing NACDS, would like to see the standards the same for dispensing technicians as pharmaceutical technicians.

Louis Ling explained that these are two entirely different types of technicians and there is no need for a dispensing technician to train for as long as a pharmaceutical technician. These regulations are just removing the education requirements that were removed for pharmaceutical technicians previously so that they would have the same educational requirements.

Board Action:

Motion: Barry Boudreaux moved to proceed with this regulation amendment as presented.

Second: Leo Basch

Action: Passed Unanimously

1. **Amendment of NAC 639.NEW** Positive Identification of User of Pharmacy Computer Systems

Larry Pinson explained the genesis of these regulation amendments and the difficulty Board staff has had in determining who was responsible for filling prescriptions during investigation of errors. Statute requires a written initial or signature of the person(s) who were responsible for filling a prescription. If electronic initials are used, as in many of the pharmacies today, then there needs to be true accountability for who actually performed those duties. Board staff has found during investigations that sometimes the persons initials that are on a prescription are those of someone not even at work that day. Board staff wants assurance that a pharmacist that logs on in the morning cannot

simply leave that computer on all day for anyone's use. Records maintained in the pharmacy need to be accurate.

Phil Burgess, of Walgreens, Vic Vercammen, of CVS, and Cookie Quandt, of Longs all appeared and voiced concerns. Specifically, each had difficulty with the language requiring a pharmacist or technician to be identified by a unique code for each time they were using the computer. They all felt the language was too restrictive. Mr. Vercammen suggested the language be flexible enough to accommodate each company's computer system and the differences in how they work. Ms. Quandt suggested the removal of five words – "must be entered each time" – and that would accommodate their concerns. They do not want the pharmacist or technician to have to sign off after each prescription is filled. They claimed it to be too cumbersome and not be in the patient's best interest since it would take too long.

Mary Ryan, representing Medco, noted that they use biometrics that automatically time out in four minutes in some of the Medco facilities and that works well. After discussion, the industry felt a time out system would work for them and that four minutes has been determined by national studies to be a reasonable time period.

Liz Macmenamin asked for a committee to study this matter.

Board Action:

Motion: Ray Seidlinger moved to proceed to Public Hearing taking into consideration the suggested changes.

Second: Barry Boudreaux

Action: Passed Unanimously

PUBLIC HEARING

15. Notice of Intent to Act Upon a Regulation:

Amendment of Nevada Administrative Code 639.NEW Compounding This new language defines the conditions and procedures under which preparation of sterile and non-sterile compounded prescription drugs are prepared.

Louis Ling reviewed the changes that had been made to the Compounding language because of the input from the last Workshop and others from the industry. Katie Craven noted that there were issues with the language that had been changed to accommodate the Hospital Association. Ms. Craven contended that it is not practical for all hospital pharmacies and she was unsure how her hospital could comply.

President Wuest opened the Public Hearing.

Phil Burgess, representing Walgreens, appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Mr. Burgess had questions regarding the definition of “compounding.” He had issues with language that addressed training, properly sealed suppositories, providing Board staff a sample, automated compounding equipment, the list of hazardous materials and acceptor isolators. After discussion Ms. Craven stated that she feels there should be a separate section for non-hazardous drugs so the all encompassing language would not affect retail pharmacy and their practice.

Liz Macmenamin, representing RAN, and Mary Staples, representing NACDS, appeared and were sworn by President Wuest prior to answering questions or offering testimony.

They testified that they did not want retail pharmacy included in this regulation and stated that they wanted the definition of compounding changed as Mr. Burgess had suggested. Ms. Macmenamin noted for the record that their pharmacists can mix two ingredients together, which would constitute compounding, without the onerous regulations as they are written.

Mark Hencher, representing Kronos, appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Mr. Hencher would like to see the regulations written in the interest of pharmacy and patient safety and would like to see the regulations passed as written.

President Wuest closed the Public Hearing.

The Board discussed various issues and as a result several sections of the language were held out for further review after another meeting with hospital pharmacy representatives.

President Wuest re-opened the Public Hearing.

Gener Tejero, representing Specialty Pharmacy, appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Mr. Tejero testified that what the Board is doing is making changes for compounding that pharmacists will like and make their jobs easier, but noted for the record that he did not like what it was doing as far as patient safety was concerned.

Mary Staples and Liz Macmenamin, already sworn, did not want the language passed but brought back to Public Hearing.

Mike Fritz and Julie Larsen, representing Renown, appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Mr. Fritz and Ms. Larsen wanted to back Katie Craven's position that they would not be able to comply with keeping records like a retail pharmacy. As for accountability for errors, Ms. Larsen stated that Renown and most hospitals have a root cause analysis system in place to determine who commits errors.

Mark Hencher, previously sworn, backed Gener Tejero's position that the Board is there to protect the public, not make it easier for themselves.

President Wuest closed the Public Hearing.

Louis Ling highlighted what was discussed and reviewed the items that would be excluded from the compounding regulation amendment as presented. The excluded items would be readdressed at meetings with hospital pharmacy personnel in both the North and South and brought back as a chaser amendment at the June Board meeting. President Wuest asked for a motion.

Board Action:

Motion: Barry Boudreaux moved to adopt the compounding regulations excluding all the sections Mr. Ling described except for section 4(2)(a)(2).

Second: Leo Basch

Amend: Katie Craven asked to amend the motion to exclude section 4(2)(a)(2) and include it in the chaser with the other sections.

After more discussion, Mr. Boudreaux accepted Ms. Craven's amendment.

Action: Passed Unanimously

16. Next Board Meeting:

June 6 & 7, 2007 – Las Vegas, Nevada

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

There were no public comments.