

BOARD MEETING

Las Vegas Chamber of Commerce  
3720 Howard Hughes Parkway  
Las Vegas

Wednesday, July 25, 2007  
and  
Thursday, July 26, 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:

Board Staff Present:

Larry Pinson

Jeri Walter

Louis Ling

Nancy Savage

CONSENT AGENDA

1. Approval of June 6-7, 2007, Minutes
2. Applications for Out-of-State MDEG – Non Appearance:
  - A. Blink Twice Inc. – New York, NY
  - B. Smiths Medical ASD, Inc. – Dublin, OH
  - C. Smiths Medical ASD, Inc. – Gary, IN
  - D. Smtihs Medical (Medex Cardio-Pulmonary, Inc.) – Vernon Hills, IL

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

- E. Bellevue Pharmacy Solutions – St. Louis, MO
- F. Crescent Healthcare, Inc. – Hayward, CA
- G. CVS ProCare Pharmacy #2915 – Kailua, HI

- H. Injured Workers Pharmacy, LLC – Methuen, MA
- I. MedTech Diagnostic Services – Ft Myers, FL
- J. Oncomed Pharmaceutical Services – Manhasset, NY
- K. Pharmcore – Hallandale, FL
- L. Prescription Plus, Inc. – Wellington, FL
- M. Professional Pharmacy – Long Beach, CA

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

- N. Accredo Health Group, Inc. – Nashville, TN
- O. Dendreon Corporation – Morris Plains, NJ
- P. Nostrum Laboratories, Inc. – Kansas City, MO
- Q. Novartis Pharmaceuticals Corporation – East Hanover, NJ
- R. Patterson Logistic Services, Inc. – Kent, WA
- S. Western Research Laboratories – Tempe, AZ

Applications for Nevada MDEG – Non Appearance:

- T. Campbell Wellness Center – Las Vegas
- U. Cranial Technologies, Inc. – Las Vegas
- V. Helt Medical Equipment Inc. – Las Vegas
- W. JC Medical Supplies Inc. – Las Vegas
- X. Lev's Medical Supply – Las Vegas
- Y. Medical N Mobility Henderson, LLC – Henderson
- Z. Oasis Medical Supply – Las Vegas
- AA. Pahrump Medical Supply Inc. – Pahrump
- BB. Pro Care Medical of Las Vegas Inc. – Las Vegas
- CC. Sierra Medical, LLC – Incline Village

Application for Nevada Wholesaler – Non Appearance:

- DD. Nevada Medical and Surgical Supply Corp. – Las Vegas

Applications for Nevada Pharmacy – Non Appearance:

- EE. CVS/pharmacy #82 – North Las Vegas
- FF. Walgreens #011444 – Henderson
- GG. Walgreens Home Care – Las Vegas
- HH. Wal-Mart Pharmacy #10-4339 – North Las Vegas

Board Action:

Motion: Katie Craven moved to approve the minutes of the June 6<sup>th</sup> and 7<sup>th</sup>, 2007 Board meeting.

Second: Leo Basch

Action: Passed Unanimously

Discussion:

The consent agenda applications and supporting documents were reviewed.

NOTE: Leo Basch recused from participation in the vote on Walgreens items 2GG and FF. Keith Macdonald recused from participation in the vote on Wal-Mart item 2HH. Barry Boudreaux recused from participation in the vote on Medco item 2N

Board Action:

Motion: Barry Boudreaux read the information related to the consent items and found the information to be accurate and complete and moved for approval of item 2 with the exception of 2GG, HH, FF and N.

Discussion: The Board determined they would like an appearance from Nevada Medical and Surgical Supply Corporation to have them explain their operation.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Katie Craven moved to approve item 2N.

Second: Leo Basch

Action: Passed Unanimously

Motion: Ray Seidlinger moved to approve items 2GG and FF.

Second: Barry Boudreaux

Action: Passed Unanimously

Motion: Ray Seidlinger moved to approve item 2HH

Second: Leo Basch

Action: Passed Unanimously

REGULAR AGENDA

3. Application for Nevada Pharmacy – Appearance:
  - A. Assured Pharmacy Las Vegas Inc. – Las Vegas

John Eric Mudder appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Mr. Mudder explained that they will cater to pain management patients. They have a tight relationship with physicians and their patients. They will use a check and balance system where the prescription could be transmitted electronically to the pharmacy to begin the filling process. The patient then brings in the original prescription when they come to pick up the prescription. They primarily serve pain management patients for workman's compensation.

The Board questioned Mr. Mudder regarding an Oregon action and he explained that they had terminated a managing pharmacist and the new managing pharmacist did not do an inventory within ten days. They were fined \$5,000.00 and the pharmacist was fined \$1,000.00.

Mr. Mudder reviewed his work history for the Board.

Board Action:

Motion: Keith Macdonald moved to approve the application for pharmacy pending inspection.

Second: Katie Craven

Action: Passed Unanimously

B. Centennial Hills Hospital Medical Center – Las Vegas

Karen Follis appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Ms. Follis explained that she is the Associate Administrator of Valley Health Systems and they have five hospitals registered in Nevada. This will be an acute care hospital with 165 beds with no pediatric care. They are USP/797 compliant and the pharmacy will be open from 7:00 a.m. to 7:00 p.m. Since they have no NICU they do not see a need for a 24 hour pharmacy.

Board Action:

Motion: Leo Basch moved to accept the application for pharmacy pending inspection.

Second: Katie Craven

Action: Passed Unanimously

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

University of Arizona College of Pharmacy – Tucson, AZ

Larry Pinson presented the application from the University of Arizona that was tabled for further review by Staff at the June Board meeting. The University of Arizona has been asked to provide MTM for various insurance companies and would very often have nothing to do with the actual filling/dispensing process. They did not know if a Nevada license was required for this activity, so they made application.

Board Action:

Motion: Leo Basch moved to approve the application for the University of Arizona.

Second: Keith Macdonald

Action: Passed Unanimously

5. Disciplinary Action

- A. Pamela S. Goff, R.Ph (06-069A-RPH-S)
- B. Nazanin Rezvan, R.Ph (06-069B-RPH-S)
- C. Jackson Yu, R.Ph (06-069C-RPH-S)
- D. Asia I. Cornelius, PT (06-069-PT-S)
- E. Summerlin Hospital Medical Center Pharmacy (06-069-IA-S)

Rob Graham appeared and represented Pamela Goff. Wendy Cozal, appeared and represented Jackson Yu as his personal counsel. John Bailey appeared and represented Nazanin Rezvan, Jackson Yu and Asia Cornelius. Michael Prang and Ken Webster appeared and represented Summerlin Hospital Medical Center Pharmacy.

Board counsel, Louis Ling introduced four exhibits:

- Exhibit 1 Neonatal TPN Orders
- Exhibit 2 BAXA Micro Compounder
- Exhibit 3 Event Log Report
- Exhibit 4 Summerlin Hospital MM23 Black Box Data

All four exhibits were admitted into evidence.

Mr. Graham, Ms. Cozal, Mr. Bailey, and Mr. Prang all gave opening statements and all concurred with the gravity of the error that caused Alyssa Shinn's death and how each of their clients have changed their practice of pharmacy to ensure an error of this nature does not happen again.

Mr. Ling called Pamela Goff, Nazanin Rezvan, Jackson Yu, Asia Cornelius, Gretta Woodington and Kathleen Shinn to testify. The following is a summary of the hearing based on testimony and presentations of the parties.

On October 19, 2006, Alyssa Shinn was born to Mr. and Mrs. Shinn at Summerlin Hospital. Alyssa Shinn was born prematurely, weighing slightly over one pound at birth, and was placed in the Neonatal Intensive Care Unit (NICU) at Summerlin Hospital. Alyssa Shinn was under the care and treatment of Dr. Zenteno.

As part of Alyssa Shinn's care, Dr. Zenteno had ordered that Alyssa Shinn receive total parenteral nutrition (TPN), and those TPN orders were compounded by Summerlin Pharmacy. Per Summerlin Pharmacy's policies and procedures, compounded orders such as TPN orders were to be received by the Summerlin Pharmacy by 5:00 p.m. each night.

On November 8, 2006, Dr. Zenteno created a written order for TPN for Alyssa Shinn. The written order showed that Dr. Zenteno created the order at 4:30 p.m., but the order was not scanned into the computer system and received by the pharmacy until well after 5:00 p.m. One of the components included in the TPN order for Alyssa Shinn was zinc, written by Dr. Zenteno for the concentration of 330 mcg./100 ml.

At 7:44 p.m., Ms. Goff processed the TPN order for Alyssa Shinn into the pharmacy's computer system. Because Dr. Zenteno's order for the zinc was written in quantity per volume rather than in quantity per patient weight, and because Summerlin Pharmacy's automated TPN compounding device (known as BAXA device) was set up for orders to be placed in quantity per weight, Ms. Goff calculated the total volume for the bag that would contain the finished TPN, and then performed a calculation to convert Dr. Zenteno's zinc order as appropriate for the total volume of the bag. Ms. Goff performed this first calculation correctly, but because there had been concerns raised by the nursing staff regarding the quantity per volume calculations appearing on TPN labels, Ms. Goff recalculated the zinc order to convert it from mcgs./deciliter to mcgs./kilogram. In recalculating the zinc order, Ms. Goff selected "mg." for the quantity rather than "mcg." as ordered, thus resulting in a final quantity of zinc of 330 mg. per 100 ml. rather than 330 mcg. per 100 ml. Thus, when Ms. Goff printed the two label sets for the preparation of Alyssa Shinn's TPN order per Summerlin Hospital's policies and procedures, the labels contained an incorrect dose of zinc that was one thousand times more than ordered.

After creating the two label sets, Ms. Goff presented the label sets to Ms. Rezvan for double-checking of the accuracy of the data entered by Ms. Goff. Such double-checking is required by Summerlin Pharmacy's policy and procedure for TPN's. Ms. Rezvan received Alyssa Shinn's TPN order, but, in violation of Summerlin Pharmacy's policy, did not place her initial on the label sets. Ms. Rezvan failed to catch the error Ms. Goff had committed regarding Alyssa Shinn's TPN order. Ms. Rezvan explained that she simply did not notice the "mg." instead of the "mcg." that should have been on the zinc component of the order. After completing her check of the order, per Summerlin Pharmacy's procedure, Ms. Rezvan forwarded the label sets to the compounding room so that the order could be filled.

Ms. Cornelius was the pharmaceutical technician who performed the compounding on November 8, 2006. Ms. Cornelius was asked to compound a few products on

November 8, 2006 because the usual compounding pharmaceutical technician was unavailable that night.

Ms. Cornelius' testimony and the testimony of the pharmacists who worked with her or who supervised her showed that Ms. Cornelius was poorly trained regarding the compounding of products using the BAXA device. Several of the pharmacist who worked with Ms. Cornelius gave specific instances where Ms. Cornelius made errors in filling prescription orders. According to Ms. Cornelius, her training consisted of watching another technician use the BAXA device for about one week. Ms. Cornelius explained that prior to compounding Alyssa Shinn's TPN, she had compounded fewer than 20 products using the BAXA device. Ms. Cornelius testified that she had not replenished a syringe on the BAXA device before the night of November 8, 2006, and she was so poorly trained and unknowledgeable that she did not sense or understand anything was wrong with Alyssa Shinn's TPN processing even though she replenished the zinc syringe numerous times. At hearing, Ms. Cornelius' testimony created the impression that she was sincere in her ignorance, but that her ignorance was profound. The testimony also showed that Summerlin Pharmacy had been told by its staff about concerns with Ms. Cornelius' competence and ignorance, but, nonetheless, Ms. Cornelius was allowed to compound TPNs by Summerlin Pharmacy.

When Ms. Cornelius compounded Alyssa Shinn's TPN, she was required because of the total calculated volume to use a 500 ml. bag rather than the 250 ml. bag that was usual for neonatal patients. Ms. Cornelius replenished the zinc supply in the BAXA device eleven times in the course of making Alyssa Shinn's TPN, accounting for 45 – 48 vials of zinc. Even though such a quantity of zinc was unprecedented to Ms. Cornelius, she did not speak of her knowledge or concerns regarding the zinc to any pharmacist on duty on the evening of November 8, 2006. As part of preparing Alyssa Shinn's TPN order, Ms. Cornelius manually added two ingredients beyond those that were placed in the bag by the BAXA device. Per Summerlin Pharmacy policy and procedure, when Ms. Cornelius completed the compounding of Alyssa Shinn's TPN order, she presented the bag on which one of the two label sets had been placed, the duplicate label set, and the vials and syringes for the two manually-added ingredients to Mr. Yu for his verification. Ms. Cornelius explained that she did not tell Mr. Yu or any other pharmacist about the huge quantity of zinc she had added to Alyssa Shinn's TPN because she did not know or think there was anything wrong with what she had done.

Mr. Yu verified Alyssa Shinn's TPN order presented to him by Ms. Cornelius. At the time, Summerlin Pharmacy's policy and procedure required the verifying pharmacist to verify only the vials and syringes of the manually added ingredients, but did not require the verifying pharmacist to compare the completed TPN product with the order to verify whether the completed TPN product was compliant with the order. When Mr. Yu verified Alyssa Shinn's TPN order as filled by Ms. Cornelius, he performed the verification according to Summerlin Pharmacy's policy and procedure, thus performing a verification limited to verifying the vials and syringes of the manually added ingredients. Because Ms. Cornelius did not inform Mr. Yu of the unusual quantity of zinc she had used, and because the zinc was not manually added but added to the bag by the BAXA device, and because Mr. Yu performed only the limited verification required of him by

Summerlin Pharmacy, Mr. Yu did not catch that Alyssa Shinn's TPN bag contained a one thousand times overdose of zinc.

Mr. Yu explained that he followed Summerlin Pharmacy's policy and procedure rigidly and that he looked only at Alyssa Shinn's identifying information at the top of the BAXA printout and at the manual additive information on the bottom of the printout and that he did not look at any of the ingredient information in the middle of the printout. Mr. Yu admitted that there were several clues that something about Alyssa Shinn's order was wrong, including the large size of the IV bag and the clear statement on the printout – had he read it – that the bag contained 481.80 mls. of zinc in a bag that contained a total of 580 mls. In close questioning from several Board members, Mr. Yu revealed that his "verification" was really cursory, since he admitted that he did not seek out any information beyond the BAXA printout, which did not include Alyssa Shinn's weight, and had he examined the manual additives more closely he would have seen that even they were not calculated properly. Nonetheless, throughout his testimony, Mr. Yu insisted that he bore no responsibility for the error regarding Alyssa Shinn's TPN because he had followed Summerlin Pharmacy's policy and procedure, even though his verification failed to catch the calculation errors on the few items he admits he did check, namely the manual additives.

After verifying Alyssa Shinn's TPN bag, Mr. Yu gave it back to Ms. Cornelius for her to manually add the manual additives. Ms. Cornelius made the manual additions to Alyssa Shinn's TPN bag and sent it to the NICU for administration to Alyssa Shinn. At approximately 3:00 a.m. on November 9, 2006, nursing staff at the NICU began administration of the TPN bag that contained the zinc overdose.

On November 9, 2006 at approximately 6:00 a.m., Ms. Cornelius was going off shift and Rebecca Weiss, a lead pharmaceutical technician, was coming on shift. In the course of discussing the previous evenings work, Ms. Cornelius related to Ms. Weiss the unusual preparation of Alyssa Shinn's TPN order because Ms. Cornelius had to replenish the zinc in the BAXA machine numerous times to create the TPN bag. Ms. Weiss immediately rechecked Alyssa Shinn's order where she discovered the zinc overdosage, and took her concerns to Mr. Yu. At approximately 6:15 a.m. on November 9, 2006, Mr. Yu contacted the NICU and ordered that Alyssa Shinn's TPN be immediately discontinued, which it was. Mr. Yu thereafter contacted the managing pharmacist for Summerlin Pharmacy, Gretta Woodington, and the poison control center and began internet research to determine whether there was an antidote for a zinc overdose. The possible antidote was determined to be EDTA. Some time after 8:00 a.m., when Mr. Yu went off shift and left Summerlin Pharmacy, a compounded order for EDTA was received from a private retail pharmacy, since Summerlin did not stock EDTA, and was administered to Alyssa Shinn. Unfortunately, the EDTA did not reverse Alyssa Shinn's overdose. At approximately 4:20 p.m. on November 9, 2006, Alyssa Shinn was declared dead. The Clark County Coroner ruled that the cause of Alyssa Shinn's death was zinc intoxication.

Ms. Woodington testified that she took over in July 2006 as the seventh managing pharmacist in approximately four years as a result of being hired as a consultant when Summerlin Hospital made the transition from a contract operator of the pharmacy to

Summerlin retaking management of the pharmacy. Ms. Woodington testified that she had been reviewing and changing all of the pharmacy's operations and that, unfortunately, review and changes to the TPN compounding process had not yet made it to her attention by November 8, 2006. Ms. Woodington testified that the day after Alyssa Shinn's death, November 10, 2006, she conducted a root-cause analysis regarding the error. As a result of the error, she instituted several changes in policy. One change was to add "hard stops" and "medium stops" into the BAXA devices computer programming. A "hard stop" would not allow pharmacy personnel to go forward with the compounding when the amount of a component was too high. A "medium stop" would require a pharmacist review and intervention before the order could be further processed when the amount of a component had crossed a threshold indicating an inappropriate dose. Ms. Woodington also changed the policy regarding TPNs to require that trace minerals be manually added and no longer included in the BAXA compounding. Ms. Woodington also changed Summerlin Pharmacy's policy and procedure regarding the final verification of a TPN by a pharmacist so that the pharmacist is now required to review the entire order and compare the order with the printout and label from the BAXA device. Finally, Ms. Woodington explained that Summerlin Hospital changed the Neonatal TPN Order form so that all of the routine components of a neonatal TPN were required to be written consistently with the templates contained in the BAXA device so that all physicians ordering neonatal TPNs must now write the orders in a way that no recalculation by pharmacy or nursing staff will be required.

Mrs. Shinn told the Board that she is a practicing nurse of many years' experience, so she understood medically what had happened with her throughout her and her husband's attempts to conceive, the complications with her pregnancy, and Alyssa's medical condition. Mrs. Shinn testified that she and Richard had determined to start a family and that their first pregnancy terminated by miscarriage. Ms. Shinn explained that Alyssa was conceived as the result of a lengthy and costly process of *in vitro* fertilization and that her pregnancy was difficult and complicated. Alyssa was born prematurely by caesarian section because of medical complications that threatened Mrs. Shinn's and Alyssa's life. When Alyssa was born, she was one pound, four ounces. Mrs. Shinn explained that up to November 8, 2006, Alyssa was progressing well. Alyssa was able to breathe without a respirator, had just begun consuming some milk provided by Mrs. Shinn, and had gained almost three-fourths of a pound. Thus, according to Ms. Shinn, up until the zinc overdose, all signs regarding Alyssa seemed to be positive.

Mr. Graham, Ms. Cozal, Mr. Bailey, and Mr. Prang gave closing statements and Mr. Ling gave a closing statement and recommendations.

President Wuest gave his views on the case and Keith Macdonald gave his view on pharmaceutical technicians receiving discipline. Mr. Macdonald does not think the Board should discipline pharmaceutical technicians, that pharmacists are ultimately responsible for pharmaceutical technicians work, and the pharmacy employer should discipline the pharmaceutical technician.

Board Action:

Motion: Keith Macdonald moved to dismiss the Cause of Action against Aisa Cornelius.

Second: Barry Boudreaux

Discussion: Katie Craven and Leo Basch both agreed that Ms. Cornelius should bear some responsibility and should have had some sense that there was a problem and addressed it with a pharmacist. President Wuest indicated that Summerlin erred by allowing Ms. Cornelius in the IV room since she was not properly trained.

Action: Three Board members voted for the motion, three Board members voted against the motion, and President Wuest voted for the motion. The motion passed and the Cause of Action regarding Ms. Cornelius is dismissed.

Board Action:

Motion: Leo Basch moved to find Pam Goff guilty of the alleged violations.

Second: Katie Craven

Action: Passed Unanimously

Motion: Katie Craven moved to fine Ms. Goff \$5,000.00, have her go through the Your Success Rx program at her own expense, and be on one year probation.

Second: Ray Seidlinger

Amendment: Keith Macdonald moved to amend the motion by reducing the fine to \$2,500 plus payment of the Your Success Rx program.

The amendment was not accepted by the First or the Second.

Action: Passed Unanimously

Motion: Leo Basch moved to find Nazanin Rezvan guilty of the alleged violations.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Leo Basch moved to fine Ms. Rezvan \$5,000.00, place her on 30 days suspension and have her go through the Your Success Rx program.

Second: Keith Macdonald

Amendment: Katie Craven moved to amend the motion by reducing the fine to \$2,500.00 and no 30 day suspension.

Leo Basch accepted the reduction of the fine, but not the suspension.  
Keith Macdonald accepted Leo Basch's amended amendment.

Action: Three voted to accept the motion and two voted against the motion. The motion passed.

Motion: Katie Craven moved to find Jackson Yu guilty of the alleged violations.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Katie Craven moved to fine Mr. Yu \$2,500.00, require him to take the Your Success Rx program at his own expense, and do 10 hours of CE on TPN or pharmacy errors due to Board staff within 90 days of the Board's Order. The 10 hours of CE will be in addition to the regular 30 that are due at renewal of his license.

Second: Ray Seidlinger

Amendment: Leo Basch moved to amend the motion by adding a 30 day suspension.

The amendment was accepted by the First and the Second.

Action: Passed Unanimously

Motion: Keith Macdonald moved to find Summerlin Pharmacy guilty of the alleged violations.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Keith Macdonald moved to fine Summerlin Pharmacy \$10,000.00 plus the fees and costs in this matter and participate in the Your Success Rx program at their own expense.

Second: Ann Peterson

Amendment: Katie Craven moved to amend the motion to include a Your Success Rx follow-up in one year to see how the pharmacy is operating.

The amendment was accepted by the First and the Second.

Action: Passed Unanimously

F. Wendell C. Weeks, R.Ph  
G. Walgreens #04137

(06-044-RPH-S)  
(06-044-PH-S)

A stipulated agreement was presented to Mr. Weeks and Walgreens #04137 and both signed the stipulated agreements accepting the terms of a \$200.00 fine for an ingested misfill.

Board Action:

Motion: Keith Macdonald moved to accept the stipulated agreements as presented.

Second: Ray Seidlinger

Action: Passed Unanimously

6. Requests for Technician in Training Registration – Appearance:

A. Seth Dines

Seth Dines appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Mr. Dines is currently enrolled in the Milan Institute participating in their pharmaceutical technician program. When he was asked to complete an application for pharmaceutical technician-in-training he indicated that he had been arrested for delinquency of a minor, speed contest and possession of marijuana.

Mr. Dines explained that he served 30 days in jail for delinquency of a minor and speed contest. He was dating a girl under 18 and she was in the car at the time of his arrest for speed contest. Regarding the possession of marijuana, Mr. Dines indicated that he used marijuana because of depression. He has since been in treatment and is now taking antidepressants rather than using marijuana.

Board Action:

Motion: Keith Macdonald moved to approve Mr. Dines application for pharmaceutical technician-in-training pending a PRN-PRN evaluation.

Second: Ray Seidlinger

Action: Passed Unanimously

B. Alicia Richins

Alicia Richins appeared and was sworn by President Wuest prior to answering questions or offering testimony.

Ms. Richins is currently enrolled in the Milan Institute participating in their pharmaceutical technician program. When she was asked to complete an application for pharmaceutical technician-in-training she indicated that she had been arrested in May, 2005, and spent six days in jail for possession of drug paraphernalia. She claims to have used methamphetamine twice.

Ms. Richins stated that she has been diagnosed as bi-polar and is now on medication. She is being treated at Northern Nevada Adult Mental Health. She is dedicated to her training at Milan and is looking forward to a career as a pharmaceutical technician.

Board Action:

Motion: Keith Macdonald moved to approve Ms. Richins application for pharmaceutical technician-in-training pending a PRN-PRN evaluation.

Second: Ray Seidlinger

Action: Passed Unanimously

C. Albert Gomes

Mr. Gomes cancelled his appearance.

D. Richard Burchinal

Mr. Burchinal cancelled his appearance.

7. Request for Reinstatement of Pharmacy Technician License – Appearance:

Cynthia L. Blake

Cynthia Blake did not appear. She did not call or cancel her appearance.

8. Request for Reinstatement of Pharmacist License – Appearance:

Paul L. Hampton

Paul Hampton and Larry Espadero, PRN-PRN monitor, appeared and were sworn by President Wuest prior to answering questions or offering testimony.

Mr. Espadero advised the Board that Mr. Hampton is in compliance with his PRN-PRN program and recommends that Mr. Hampton's license be reinstated. The Board questioned Mr. Hampton regarding how he feels about going back into pharmacy practice. Mr. Hampton answered their questions to the Board's satisfaction.

Board Action:

Motion: Katie Craven moved to reinstate Mr. Hampton's pharmacist license.

Second: Barry Boudreaux

Action: Passed Unanimously

9. Appearance Requests:

A. Mary Ryan – Off-Site Counseling

Mary Ryan, representing Medco, appeared and gave a presentation regarding alternative pharmacy practice sites. They have a concept that would allow some functions performed by pharmacists and technicians from a non-pharmacy setting by using a computer with access to Medco data. They would have complete audit trails for all functions and they would be HIPPA compliant. There are seven states that have approved or deployed this concept. After her presentation she asked if the Board would consider adopting this concept.

Keith Macdonald recommended that Board staff write regs to include this concept tied to a pharmacy. Ms. Ryan stated that Florida and Texas have regulations and California has a brief paragraph to allow this concept. It was also suggested to broaden the language to include call centers at the same time.

B. Bruce Erickson, R.Ph, MS – Intelligent Hospital Systems

Bruce Erickson appeared and gave a presentation on Robotic IV Automation (RIVA). Mr. Erickson noted that this is the new standard in IV admixture compounding that is safe and efficient. He gave the design specifications and described RIVA in detail for the Board.

10. Executive Secretary Report:

- A. Financial Report
  - 1. 2007/2008 Budget
- B. Investment Report

Larry Pinson gave the financial and investment reports to the Board's satisfaction. Mr. Pinson also presented the budget for fiscal year 2007-2008.

Board Action:

Motion: Keith Macdonald moved to approve the Board's budget for fiscal year 2007-2008.

Second: Katie Craven

Action: Passed Unanimously

C. Temporary Licenses

Mr. Pinson granted four temporary licenses since the June Board meeting.

D. Staff Activities

1. Meetings

Larry Pinson advised the Board that he was doing a lot of CE programs between now and pharmacist's renewals in October. If anyone is looking for a law CE program to attend he advised them to go to our website for dates, locations and times.

Louis Ling and Larry Pinson presented Nevada's E-Pedigree program at the California State Board of Pharmacy meeting in Los Angeles which was well received. Mr. Ling and Mr. Pinson plan to contact NABP to see if they would be willing to house the program.

2. Miscellaneous

a. Board Office

President Wuest advised the Board that Board staff is negotiating a lease for a new office location. It will be more centrally located, more room, and less per square foot than we are paying now. President Wuest asked the Board for a motion to approve the move.

Board Action:

Motion: Keith Macdonald moved to approve the move to a new Board office location.

Second: Katie Craven

Action: Passed Unanimously

b. Staff

Larry Pinson advised the Board, after discussions with Mr. Basch, that he is considering adding another pharmacist/inspector to take on special projects as well as help our current extremely busy inspectors.

c. Approved CE Program

Mr. Pinson approved one CE program for pharmacists that had CME credit approval.

E. Report to Board

1. The "Green Sign"

Larry Pinson gave the Board three choices of the Nevada version of the North Carolina green sign that he presented at the June meeting. He advised the Board that North Carolina was OK with Nevada using their concept. Ann Peterson will develop the final sign language and will advise Mr. Pinson.

2. Telepharmacy

Larry Pinson checked with the Nursing Board as requested by the Board as to how they handle telepharmacy. The Nursing Board allows no telenursing whatsoever unless the practitioner is licensed by Nevada.

3. Tamper-proof Medication Disposal Containers

Mr. Pinson advised the Board a “wait and see” approach based on the difficulties that Washington is experiencing regarding this concept.

F. Tamper-proof Rx Pads

Mr. Pinson advised the Board that tamper-proof prescription pads are going to be required for Medicaid patients on October 1, 2007, and that Board staff is not inclined to write regulations to accommodate one insurance company.

Dan Luce and Liz Macmenamin agreed that it was not a Board of Pharmacy issue but if they do not have a prescription on tamper-proof pads by October 1, 2007, the pharmacies will have to deny service to Medicaid patients because they will not be able to comply. They have been trying to get the requirement date pushed back so doctors have an opportunity to stock the required pads. They noted that it took 18 months to get this requirement operational in New York.

G. Immunization Report

Mr. Pinson asked Ray Seidlinger to look into immunization reporting.

H. Activities Report

The Activities Report for the June meeting was in the Board book for Board review.

11. General Counsel Report

Louis Ling reported that he went to Boston and spoke at the HDMA meeting on e-pedigrees and the talk went well.

WORKSHOP

12. 1. **Amendment of NAC 639.NEW LANGUAGE** Compounding Regulations

Larry Pinson updated the Board on the video conference the Compounding Committee held since the last Board meeting. Mr. Pinson announced that they came to agreement on almost all of the areas that have been at issue.

Katie Craven provided more changes which were distributed to the Board for their review. Ms. Craven also changed the language further to incorporate hard stops to compounding devices as a result of the Summerlin case.

Louis Ling explained that the regs in the Board book is a combination of the previously adopted reg and the chaser. He advised that Katie Craven put everything together and did a commendable job. Larry Pinson read into the record comments from Robin Keith who represents the rural pharmacies.

Liz Macmenamin, representing RAN, and Vic Vercammen, representing Super Value, appeared. Ms. Macmenamin noted that her members were concerned that they could not comply with the regulations as written for a simple mixing of two creams. She indicated that her members would accept a letter from Board staff allowing for a waiver to exclude retail pharmacies. Katie Craven noted that even a simple cream product should have trained people doing the compounding. Mr. Vercammen is concerned with the 5% variance. The language that requires a compounded product to be “palatable” is going to be difficult to enforce because some things never taste good. Keith Macdonald asked about documentation, etc., for magic mouthwash.

Nancy Bridges, representing Bill Welch and the Nevada Hospital Association, and Julie Larsen of Renown, appeared. Ms. Bridges indicated that she and Mr. Welch had no problem with moving forward with the language as written. Ms. Larsen noted that the + or – 3% variance could not be attained by all automated compounding devices but indicated that they were more accurate than gravity. She suggested perhaps we could define automated compounding device.

President Wuest asked David Vasenden of Don’s Pharmacy if his patients will encounter difficulty in getting a product they have been taking for years because of this language. Mr. Vasenden said that there is a possibility without the 797 language that allows a pharmacist to use his professional judgment.

Genner Tejero stated that he uses a homeopathic product that is not FDA approved. He gets certification of authenticity on some of his products but he will have to research a few of the products he uses. Mr. Tejero noted that there is a 795 standard that Mr. Ling could incorporate into this language that would address this problem.

The Board addressed Katie Craven’s new language delineated in blue text that was e-mailed to the Board and all that have been involved in the Compounding meetings. Leo Basch did some clean up on the language and did some comparison with what was in the Board book and Ms. Craven’s language.

Board Action:

Motion: Ray Seidlinger moved to take the Compounding regulations to Public Hearing.

Second: Katie Craven

Action: Passed Unanimously

2. **Amendment of NAC 639.NEW LANGUAGE** Controlled substance issues related to veterinarians.

Louis Ling explained that the Veterinary Board requested we add language to incorporate record keeping requirements for veterinarians. The Veterinary Board has hired an inspector and veterinarians will now be inspected biennially. They have found two veterinarians that had written prescriptions for their own dogs, took the prescriptions to the pharmacy and had them filled and abused the drugs by taking them for their personal use. It has long been known that some veterinarians and technicians have abused Ketamine which the Board scheduled several years ago in hopes of stopping the abuse. The Veterinary Board wants a uniform set of rules for veterinarians and request these regulations be passed.

Board Action:

Motion: Keith Macdonald moved to proceed to Public Hearing with these regulations.

Second: Ray Seidlinger

Action: Passed Unanimously

1. **Amendment of NAC 639.NEW LANGUAGE** Implementation of AB128 regarding sale practices of manufacturers and wholesalers.

Louis Ling presented the regulation and explained that this concept was mandated by the Legislature. Board staff is trying to set the requirements for manufacturer and wholesaler reporting to the Board. Mr. Ling suggested that perhaps the Board might want to use the code of conduct used by Pharma.

Joe Brown, of Jones Vargas, and Katie Fellows representing Pharma appeared. They had issue with number six and stated that the language was too broad and goes beyond the authority of the Board of Pharmacy. They submitted a letter and questioned how the Board thought they had authority to review any of the reports submitted.

Tom Tremble, of Advanced Medical Technology Associates, appeared and challenged the Board as to their authority over DME wholesalers. Mr. Tremble claimed that it would not be appropriate for DME people to have to adhere to Pharma's code of conduct. DME has their own code that they abide by and he provided a copy to Board staff.

Board staff asked for time to contact the legislator who wrote AB128 and find out the intent of the legislation and bring it back to Workshop in September.

Board Action:

Motion: Keith Macdonald moved to have Board staff meet with the author of the Bill and to incorporate the DME code of ethics into the language.

Second: Ann Peterson

Action: Passed Unanimously

4. **Amendment of NAC 639.593** Modifying fingerprint requirements for wholesalers.

The Board discussed requiring wholesalers submit fingerprints electronically. There was no public comment.

Board Action:

Motion: Ray Seidlinger moved to proceed to Public Hearing.

Second: Ann Peterson

Action: Passed Unanimously

5. **Amendment of NAC 639.NEW LANGUAGE** Positive identification of user of pharmacy computer system.

Louis Ling reviewed the changes to the language that were derived from input from the June Board meeting.

Liz Macmenamin, of RAN, and Mary Staples, of NACDS, noted that they were under the impression from the June meeting that the 4 minute rule would be removed from this language and it is still there. Neither Ms. Macmenamin or Ms. Staples like the language that will hold the pharmacy responsible for the failure of a pharmacist not to log off the computer. They did, however, commend Board staff for noting in the Newsletter that it is the pharmacist's responsibility to keep their passwords secure.

Dan Luce, of Walgreens, and Vic Vercammen, of Super Value, appeared. Mr. Luce noted that the federal government is moving toward electronic everything. Part D will be all electronic, thus eliminating paper. He stated that the Board should not strap the pharmacist with these requirements, as it hinders patient care, for the few times when Board staff is doing an investigation and can not determine who made an error.

The Board discussed the language and the suggestions made by NACDS and others to determine the direction they would like to take.

Board Action:

Motion: Keith Macdonald moved to rework the language and re-workshop to include, 1) leave pharmacy responsibility in, 2) remove the 4 minute rule, 3) include paragraph 4 that NACDS suggested – sub (a) is OK but sub (b) ties the Board’s hands and is not OK as written, and 4) allow technicians to input addresses in the computer.

Second: Ray Seidlinger

Action: Passed With One Negative Vote

PUBLIC HEARING

13. Notice of Intent to Act Upon a Regulation:

**Amendment of NAC 639.4914 and 639.4915 Off Site Cognitive Services**

This amendment will clarify the language and define remote chart order processing.

This language is meant to clarify the definition of remote chart order processing. When we originally submitted this language to LCB they changed the intent of the Board and it was not noticed until recently.

President Wuest opened the Public Hearing.

There was no public comment.

President Wuest closed the Public Hearing and asked for a vote.

Board Action:

Motion: Ray Seidlinger moved to adopt the language as presented.

Second: Leo Basch

Action: Passed With One Negative Vote

14. Next Board Meeting:

September 5-6, 2007 – Reno, Nevada

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

There were no public comments.