

February 15, 2006

AGENDA

◆ PUBLIC NOTICE ◆

NEVADA STATE BOARD OF PHARMACY

BOARD MEETING

at the

Meadow Wood Courtyard  
5851 S Virginia Street  
Reno, Nevada

Wednesday, March 1<sup>st</sup>, 2006 – 9:00 am

Thursday, March 2<sup>nd</sup>, 2006 – 9:00 am

Please Note: The Nevada State Board of Pharmacy may address agenda items out of sequence to accommodate persons appearing before the Board or to aid in the efficiency or effectiveness of the meeting.

Public comment is welcomed by the Board, but will be heard only when that item on the agenda is reached and will be limited to five minutes per person. The president may allow additional time to a given speaker as time allows and in his sole discretion.

◆ CONSENT AGENDA ◆

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

## March 2006 Board Meeting Agenda

- \* 1. Approval of January 11-12, 2006, Minutes
- \* 2. Applications for Out-of-State MDEG – Non Appearance:
  - A. AbleNet Inc. – Roseville, MN
  - B. EBI, L.P. – Parsippany, NJ
  - C. Orbit Medical Inc. – Salt Lake City, UT
  - D. Rehabicare, A Division of Compex Technologies – Tampa, FL

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

- E. Biologics Inc. – Raleigh, NC
- F. Dawn National Pharmacy, Inc. – Glenview, IL
- G. Hospice Pharmacia – Sharon Hill, PA
- H. Pinnacare – Sacramento, CA
- I. Rockwell Compounding Associates, Inc. – Rye, NY
- J. US Compounding Inc. – Conway, AR
- K. Worksite Pharmacy #401 – Marysville, OH

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

- L. Harrison Healthcare Inc – Baltimore, MD
- M. Island Dental Co., Inc. – Memphis, TN
- N. Patterson Dental Supply Inc. – Rocklin, CA
- O. Schwarz Pharma Mfg Inc – Seymour, IN

### Applications for Nevada MDEG – Non Appearance:

- P. Essential Medical Equipment LLC – Las Vegas
- Q. Sizewise Rentals LLC – Las Vegas
- R. StateServ Medical of Nevada, LLC – North Las Vegas

### Applications for Nevada Pharmacy – Non Appearance:

- S. Desert View Regional Medical Center – Pahrump
- T. Smith's Pharmacy #338 – North Las Vegas

## ◆ REGULAR AGENDA ◆

- \* 3. Application for Nevada Pharmacy – Ownership Change – Appearance:
  - Lam's Pharmacy – Las Vegas

## March 2006 Board Meeting Agenda

- \* 4. Disciplinary Actions: Note – The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties.

- A. Marcie B. Mountan, R.Ph (05-032-RPH-N)
- B. Critical Care Systems, Inc. (05-032-PH-N)
- C. Sandra L. Stevens, R.Ph (06-001-RPH-N)

- \* 5. Request for Approval of Pharmacy Technician School – Appearance:

Everest College – Las Vegas

- \* 6. Requested Appearance:

EmployACT, Inc. – Samuel Anderson

- \* 7. General Counsel Report:

- A. Litigation Update
- B. Contracts Update

- \* 8. Executive Secretary Report:

- A. Financial Report
- B. Investment Report
- C. Pending Policy Questions
- D. Temporary Licenses
- E. Bill Drafts Due
- F. NABP Task Force/Committee Volunteers

### W O R K S H O P – Wednesday, March 1, 2006 – 9:00 am

- \* 9. **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 Nevada Administrative Code 639.NEW** Conditions for a pharmacist declining to fill a prescription.

2. **Amendment of Nevada Administrative Code 639.NEW Compounding.** Preparation of sterile and non-sterile compounded prescription drugs.

3. **Amendment of Nevada Administrative Code 639.7102 E-Prescribing.** Addressing security requirements for approved e-prescribing systems.

March 2006 Board Meeting Agenda

4. **Amendment of Nevada Administrative Code 639.650 Retail Sale of Veterinary Drugs.** New class of registration for feed stores and others who sell veterinary drugs at retail.
5. **Amendment of Nevada Administrative Code 639.NEW** Licensure of Canadian pharmacies to serve Nevada as out-of-state mail-order pharmacies.
6. **Amendment of Nevada Administrative Code 639.725** Allows non-pharmacists to stock automated filling devices.
7. **Amendment of Nevada Administrative Code 639.NEW** Conditions of repackaging of dispensed prescriptions.

PUBLIC HEARING – Thursday, March 2, 2006 – 9:00 am

\*10. Notice of Intent to Act Upon a Regulation:

1. **Amendment of Nevada Administrative Code NAC 639.220 Schedule of fees; penalties; applicability.** This will remove the financial burden to physicians that provide health care to underserved persons by allowing them to pay for one registration and change the address to another non-profit facility without providing a fee each time they move to a different location to provide health care to other underserved persons.
2. **Amendment of Nevada Administrative Code NAC 639.593 Licensing** This language implements SB37, the wholesaler statute that was passed this last legislative session.
3. **Amendment of Nevada Administrative Code NAC 639.945 Unprofessional conduct; owner responsible for acts of employees.** This language will include “chart orders” to be added to the unprofessional conduct regulations used in charging hospitals disciplinary matters.

11. Next Board Meeting:

April 19 & 20, 2006 – Las Vegas, Nevada

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

Note: No vote may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on an agenda as an item upon which action will be taken. (NRS 241.020)

\* Board action may be taken on these items.

## March 2006 Board Meeting Agenda

Note: We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements for the meeting are necessary, please notify the Nevada State Board of Pharmacy, 555 Double Eagle Court, Suite 1100, Reno, Nevada 89521, or call Jeri Walter at (775) 850-1440, as soon as possible.

Anyone desiring additional information regarding the meeting is invited to call the board office at (775) 850-1440.

Mailing a copy of the Nevada State Board of Pharmacy meeting agenda to any person who has requested it will not continue unless a request for reinstatement on the mailing list is made in writing every six months. Accredited Continuing Education credit of 1 hour will be given per day of Board meeting attendance of a minimum of 4 hours. A pharmacist can receive Nevada Law Credit for attending the board meeting for a minimum of 4 hours.

This notice has been posted at the following locations:

Elko County Courthouse – Elko  
Mineral County Courthouse – Hawthorne  
Washoe County Courthouse – Reno  
Nevada State Board of Pharmacy – Reno and Las Vegas

## BOARD MEETING

Meadow Wood Courtyard  
5851 S Virginia Street  
Reno, Nevada

March 1<sup>st</sup> and 2<sup>nd</sup>, 2006

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

### Board Members Present:

Dave Wuest	Keith Macdonald	Joe Kellogg
Leo Basch	Katie Craven	Ann Peterson
Ray Seidlinger		

### Board Members Absent:

### Board Staff Present:

Larry Pinson	Jeri Walter	Louis Ling	Keith Marcher
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Discussion:

The consent agenda applications and supporting documents were reviewed. It was noted that the January meeting minutes indicated that Ann Peterson was present when she was not in attendance. There were several changes Leo Basch suggested be made to the text of the minutes.

NOTE: Dave Wuest recused from Item 2 G and Joe Kellogg recused from Item 2T because they are employed by entities that also own or have interests in the particular applications.

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 items 1 and 2 with the suggested changes except for Items 2 G and T.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Katie Craven moved to accept Item 2 G.

Second: Leo Basch

Action: Passed Unanimously

Motion: Dave Wuest moved to accept Item 2 T.

Second: Ann Peterson

Action: Passed Unanimously

REGULAR AGENDA

3. Application for Nevada Pharmacy – Ownership Change – Appearance:

Lam’s Pharmacy – Las Vegas

NOTE: Katie Craven disclosed that she knows Roger Lam.

Rock Hankin and Terry Cater appeared and were sworn by President Kellogg prior to answering questions or offering testimony.

Keith Macdonald led the questioning regarding the change of ownership. Mr. Hankin indicated that he made the purchase of Lam’s as an investment in the health care industry. Mr. Macdonald noted that Lam’s is seventh in the nation as a narcotic dispensing pharmacy. Mr. Cater advised the Board that he researched this prior to purchasing Lam’s and found no discrepancies between prescriptions and wholesaler transactions.

Board Action:

Motion: Keith Macdonald moved to approve the application for change of ownership of Lam’s Pharmacy.

Second: Dave Wuest

Action: Passed Unanimously

4. Disciplinary Actions:

- A. Marcie B. Mountan, R.Ph (05-032-RPH-N)
- B. Critical Care Systems, Inc. (05-032-PH-N)

NOTE: Dave Wuest recused from participation as he had prior knowledge of the circumstances in this matter.

Marcie Mountan appeared and was sworn by President Kellogg prior to answering questions or offering testimony.

Tony Lauria was present as legal counsel to Ms. Mountan.

Mr. Lauria presented Defense Exhibits A – M.



- A. Letter of recommendation regarding Marcie Mountan
- B. Pre-Hire reference regarding Marcie Mountan from Dave Halterman of Select Security Hospital
- C. Pre-Hire reference regarding Marcie Mountan from Beth Foster of the Reno VA Hospital
- D. Pre-Hire reference regarding Marcie Mountan from Tim Stratten of the University of Montana School of Pharmacy
- E. Pre-Hire reference regarding Chanda Ekker from Kevin Desmond, Pharmacy Manager for Washoe Medical Center
- F. Pre-Hire reference regarding Chanda Ekker from Pharmacy Supervisor of Washoe Medical Center
- G. Pre-Hire reference regarding Chanda Ekker from Rebecca Adams of Washoe Medical Center
- H. Technician Orientation sheet regarding Chanda Ekker
- I. Compounding Sheet for 5-FU prescription for Patient T dated May 18, 2005
- J. Compounding Sheet for 5-FU prescription for Patient L dated May 18, 2005
- K. Letter of reference regarding Marcie Mountan from Miranda Baca
- L. 2 ml Eclipse pump filled
- M. 100 ml Eclipse pump filled

Louis Ling presented Prosecution Exhibits 1 – 5.

- 1. 2 ml Eclipse pump unfilled in package
- 2. 100 ml Eclipse pump unfilled in package
- 3. Nursing Visit Report
- 4. Unusual Occurrence Report
- 5. Washoe County Coroner Record of Death Report

Mr. Ling gave opening remarks and indicated he planned to show how the error occurred. He stated he would present testimony from an expert witness, hear from the daughter of Cindy Theiss regarding her mother's death, and show the similarity of the two Eclipse pumps. Ms. Theiss' 5-FU chemotherapy medication should have been dispensed over a 48-hour period; however, it was dispensed in 45 minutes.

Mr. Lauria gave opening remarks and agreed that the error occurred, but he said he would present the circumstances that led to the error and what changes have been implemented in the pharmacy to ensure this error never occurs again.

Chanda Ekker, pharmacy technician at CCS, appeared and was sworn by President Kellogg prior to answering questions or offering testimony.

Mr. Ling questioned Ms. Ekker.

Ms. Ekker described her career as a pharmacy technician and stated that she began working at CCS one year ago. Ms. Ekker admitted that she had no experience in

compounding chemotherapeutics, but she did compounding in general. She stated that she was familiar with Eclipse pumps being used for antibiotics, but this was the first time she had used an Eclipse pump for chemotherapeutic products. Ms. Ekker testified that she was shown the Eclipse pumps on a tour of the pharmacy, and she knew there was a volume difference but not a difference in the flow rate. Ms. Ekker stated that she chose the Eclipse ball pump for the volume. She said she was not trained on the differences of the Eclipse pump; however, she had read CCS's policies and procedures.

Ms. Ekker testified that she received the order from Ms. Mountan to compound the 5-FU chemotherapy for Ms. Theiss. She stated that she filled two orders for 5-FU that day and described her normal procedures. Ms. Ekker indicated that Ms. Mountan reviewed the paperwork by holding up the bag with the filled Eclipse pump and checking off the paperwork as she did so.

Ms. Ekker said that she found out about the error regarding Ms. Theiss' prescription when a telephone call came in, and she learned that Ms. Theiss' medication had dispensed in 45 minutes. Ms. Ekker asked a co-worker to check to see if she had done something wrong with the order and was told that she had used the wrong Eclipse pump. Ms. Ekker told Ms. Mountan and immediately fixed the other order she had filled.

Ms. Ekker testified that CCS now has the pharmacist pull the drugs and equipment for compounding and places them in the compounding room for a pharmaceutical technician to fill. She stated that CCS does not use the Eclipse ball pump any longer and now uses a bag.

Mr. Lauria cross-examined.

Mr. Lauria showed that Ms. Ekker had experience in chemotherapeutics but this was the first time she used the Eclipse pump for chemotherapeutic products. Ms. Ekker testified that she had only filled bags in the past. Ms. Ekker demonstrated how she would put the label on the pump. Mr. Lauria reviewed the difference between the two pumps and noted that the only difference in the 2 ml. pump and the 100 ml. pump is a yellow or white ring on the mouth of the pump that designated the dose time. Ms. Ekker testified that they still use the Eclipse pumps for antibiotics, but CCS does not use the pump for chemotherapeutics any longer.

The Board questioned Ms. Ekker.

Pamela Holden, registered nurse, appeared and was sworn by President Kellogg prior to answering questions or offering testimony.

Ms. Holden gave an overview of her career. She stated that she had experience with chemotherapeutics and had not used the Eclipse pump until she began work at CCS. Ms. Holden testified that she thought there was only one type Eclipse pump and that the pharmacy set the dose rate when the pump was filled. Ms. Holden was the nurse that

hooked up the 5-FU to Ms. Theiss. Ms. Holden stated that she had hooked up and deaccessed Ms. Theiss' medications in the past.

Ms. Holden was asked how she learned of the error involving Ms. Theiss. Ms. Holden stated that she received a telephone call that the pump was empty in 45 minutes. She indicated that she called Ms. Theiss to confirm that the pump was empty and telephoned Ms. Theiss' physician. Ms. Holden testified that she asked the doctor what to do and the doctor told her that this situation was not life-threatening. Ms. Holden went to Ms. Theiss' home and evaluated her. At that time, Ms. Theiss was not showing any signs of toxicity. Ms. Holden deaccessed the pump and assured Ms. Theiss the situation was not life-threatening as the doctor had told her.

Ms. Holden testified that she made notes on her care of the patient from the time of the error until the time Ms. Theiss was hospitalized. Ms. Holden stated that during the ten days before Ms. Theiss went to the hospital she showed progressive symptoms of toxicity. Ms. Holden testified that there was no antidote to a 5-FU overdose.

Mr. Lauria cross-examined and the Board questioned Ms. Holden.

David Hatzel, pharmacy manager of CCS, appeared and was sworn by President Kellogg prior to answering questions or offering testimony.

Mr. Hatzel gave an overview of his career. He testified that he had no prior experience with the Eclipse pumps or 5-FU until he began working at CCS. When he started working there, Ms. Moutan and a pharmaceutical technician showed him the Eclipse pumps and noted that there were no identifiers to distinguish chemotherapeutic Eclipse pumps and antibiotic Eclipse pumps. There were no markings on the pumps, just the boxes they came in.

Mr. Hatzel testified that he trained Chanda Ekkert when she began working at CCS and told her to be careful because the Eclipse pumps looked exactly alike. Mr. Hatzel described how he checks the Eclipse pumps after pharmacy technicians fill them. Mr. Hatzel indicated he did not know what the nurses did after the orders were filled.

Mr. Hatzel stated that he was on vacation at the time of the error and found out after his return to work. He was not notified prior to his return. Mr. Hatzel testified that he did no research to find a supportive medication or antidote and he did not speak with Ms. Theiss' physician. Mr. Hatzel advised that Darlene Hart, the nurse supervisor, did all the communication. Mr. Hatzel indicated he was aware that there were two errors that day.

Mr. Lauria cross-examined and the Board questioned Ms. Holden.

Darlene Hart, nurse and general manager for CCS, appeared and was sworn by President Kellogg prior to answering questions or offering testimony.

Ms. Hart gave an overview of her career. Ms. Hart explained that CCS changed from using CAD pumps to Eclipse pumps because they allowed the patient more mobility. Ms. Hart stated that she did not know the mechanics of how the different doses are dispensed. She said that she trained Pam Holden, but there were no policies and procedures for the Eclipse pumps until this error occurred.

Ms. Hart testified that she searched Google and Medline to see if she could find anything to do to help Ms. Theiss. She stated she found no antidote for a 5-FU overdose. The recommended treatments she found were already being implemented. Ms. Hart indicated that Drs. Schiff and Shields also evaluated and researched care of 5-FU overdoses. Ms. Hart testified that she did not know the Eclipse pumps had different flow rates.

Mr. Lauria cross-examined and the Board questioned Ms. Hart.

Marcie Mountan gave an overview of her career. Ms. Mountan stated that she was not experienced with chemotherapeutics. As an intern on rotation she spent four weeks in a pharmacy that used Eclipse pumps but she did not learn the mechanics of them. Ms. Mountan testified that she has never compounded 5-FU. She has only checked it after it was compounded by a pharmacy technician. Ms. Mountan stated that because she was of child-bearing age she did not feel comfortable compounding chemotherapeutic medications. Ms. Mountan described her procedures for checking 5-FU compounds.

Ms. Mountan described the atmosphere in the pharmacy the day of the error. She stated that they were extremely busy and she knew she was going to be practicing alone the following day so they were trying to do as much as possible in the pharmacy as they could so she would not have as much to do the following day when she was alone. Ms. Mountan described what she did to find a treatment for a patient with an overdose of 5-FU. Ms. Mountain explained that she did not contact Drs. Schiff and Shields because of her inexperience with chemotherapeutics and left that for Darlene Hart to handle.

Mr. Lauria cross-examined and the Board questioned Ms. Mountan.

Dr. Robert Ignoffo, clinical professor at UCSF, appeared and was sworn by President Kellogg prior to answering questions or offering testimony.

Dr. Ignoffo explained that he is an oncology pharmacist and teaches medical and pharmacist residents at UCSF. He stated that he has testified in courts of law as an expert witness. Dr. Ignoffo described 5-FU as an antimetabolic drug. He stated it is one of the building blocks of DNA. It inhibits one of the enzymes in cells. By inhibiting this enzyme the cell goes on to die. 5-FU has been used in the United States since the 1960's, mostly on patients with colon cancer and other cancers.

Dr. Ignoffo reviewed and chart notes and reports regarding Ms. Theiss' care. He noted that the patient was doing well in her treatment until she received the massive overdose

of 5-FU. Dr. Ignoffo stated that he would have tried to find something to combat the toxicity of the 5-FU, such as go to reference materials to see what could be done, or go to a hospital for help, or read the packaging that comes with the product, or call poison control. He stated that he would have looked for a black box warning on the package insert for the maximum daily dose and he would have begun a therapy of Neupogen to help keep Ms. Theiss' levels from falling so low. Dr. Ignoffo testified that he would have done something before ten days after the overdose.

Mr. Lauria cross-examined and the Board questioned Dr. Ignoffo.

Cindy Theiss Smith, daughter of Ms. Theiss, appeared and was sworn by President Kellogg prior to answering questions or offering testimony.

Ms. Smith stated that her mother, Ms. Theiss was diagnosed with colon cancer in December 2004. Ms. Theiss lived in Sparks and Ms. Smith lives in Fernley and Ms. Smith visited her mother every other day and spoke with her daily. Ms. Smith was very close to her mother and was uplifted that her chemotherapy treatment was successful. Ms. Theiss testified that it looked like Ms. Theiss was going to survive her cancer.

Ms. Smith stated that on the day of the overdose she contacted CCS and was told that Ms. Theiss was given an antibiotic. Later in the day, Ms. Smith was told it was an overdose of 5-FU. Ms. Smith described her mother's condition. The day after the overdose of 5-FU Ms. Theiss experienced pain in her neck and back and complained of being itchy. On the third day, Ms. Theiss broke out in a rash, was cramping, had swelling and blistering in her mouth and ears so she could not eat, had severe diarrhea, and severe nose bleeding. Ms. Smith took Ms. Theiss to the emergency room and she was given platelets. She went home and the doctors told her that the worst of her situation was over. Two days later Ms. Theiss was hospitalized because her condition was so severe she could no longer hold her head up. She was placed in ICU. The following day Ms. Theiss went in to a coma and remained that way until she died. Ms. Smith testified that during the time her mother was in a coma her skin was dark, she was losing her hair, she had a yeast infection on the exterior of her body, and she was bleeding from her cuticles. Ms. Smith stated that her mother would not get a second opinion on her condition because she trusted CCS for her care.

Mr. Lauria cross-examined Ms. Smith.

Defense witness Barbara Prosser, Vice President of Clinical Services at CCS, appeared and was sworn by President Kellogg prior to answering questions or offering testimony.

Ms. Prosser gave an overview of her career. Ms. Prosser stated she received a telephone call from Darlene Hart. She advised that the first thing they did was file an incident report, and it was evaluated by the CCS national staff. Ms. Prosser stated that action plans were put in place specifically for the Reno office.

Mr. Lauria presented another exhibit.

Exhibit N In-service training for nurses, pharmacists, etc – one for each clinical staff

Ms. Prosser testified that CCS did a complete training of staff and compiled a protocol for each level of training. She spoke with Drs. Schiff and Shields but mainly used Darlene Hart as the contact with the doctors. Ms. Prosser stated she spoke with Ms. Smith and worked with her. She said she talked with the manufacturer about why they did not color code the Eclipse ball pumps and they said that they did have a colored ring at the site where the pumps are filled. Ms. Prosser indicated that CCS is running better because of the training given their employees.

Mr. Ling cross-examined and the Board questioned Ms. Prosser.

Mr. Ling gave closing statements and recommendations. He recommended Ms. Mountan receive an appropriate fine and have her pharmacy practice evaluated by Your Success Rx at her expense within ten days of the Board's Order. Mr. Ling recommended a fine of \$10,000 for the 6<sup>th</sup> and 7<sup>th</sup> Causes of Action against CCS plus all fees and costs involved in this matter. He recommended probation of at least one year and development of policies and procedures regarding overdoses of chemotherapeutic agents, including consultation with a national expert to get the latest research materials for reference and report to the Board. Also, another condition of probation would be that CCS track errors and see if two sets of eyes can catch near misses.

Mr. Lauria made closing statements and again reiterated that they do not deny the charges. He asked the Board to consider the history of those involved. They established they had a problem and took the initiative to fix it. Mr. Lauria stated that the 1<sup>st</sup> and 2<sup>nd</sup> Cause of Action were the same, the 3<sup>rd</sup> Cause of Action is really no Cause, the 4<sup>th</sup> and 5<sup>th</sup> Cause of Action regarding the lack of training is really a Nursing Board venue rather than the Board of Pharmacy.

Board Action:

Motion: Leo Basch moved to find Marcie Mountan guilty of the First Cause of Action.

Second: Katie Craven

Action: Passed Unanimously

Motion: Ray Seidlinger moved to dismiss the Second Cause of Action against Marcie Mountan.

Second: Katie Craven

Action: Passed With One Negative Vote

Motion: Leo Basch moved to find Marcie Mountan not guilty of the Third Cause of Action.

Second: Katie Craven

Action: Passed Unanimously

Motion: Leo Basch moved to find Marcie Mountan not guilty of the Fourth Cause of Action.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Leo Basch moved to find Critical Care Systems guilty of the Fifth Cause of Action.

Second: Katie Craven

Action: Passed Unanimously

Motion: Leo Basch moved to find Critical Care Systems guilty of the Sixth and Seventh Causes of Action.

Second: Ann Peterson

Action: Passed Unanimously

After a failed motion,

Motion: Keith Macdonald moved to fine Marcie Mountan \$6,000, be placed on probation for two years, complete the Your Success Rx evaluation paying for the service with a portion of the \$6,000 fine – the balance to be paid to the State, complete ten hours of CE in addition to the required 30 units for renewal. These requirements shall be completed within 90 days of the effective day of this Order.

Second: Ann Peterson

Action: Passed Unanimously

Motion: Keith Macdonald moved to fine CCS \$10,000 total for the Fifth, Sixth and Seventh Causes of Action, be placed on probation for two years, pay all fees and costs in this matter, prepare policies and procedures and submit to Board staff, monitor errors and report to Med Watch.

Second: Leo Basch

Action: Passed Unanimously

C. Sandra L. Stevens, R.Ph (06-001-RPH-N)

Due to lack of time, this stipulated agreement was continued to the April 19<sup>th</sup> and 20<sup>th</sup>, 2006 Board meeting.

5. Request for Approval of Pharmacy Technician School – Appearance:

Everest College – Las Vegas

Sharon Miller and John Smith appeared and were sworn by President Kellogg prior to answering questions or offering testimony.

Ms. Miller and Mr. Smith noted that the Las Vegas College will be changed to Everest College. They requested Board approval of a PT program. They testified that it was a 720 hour program plus 48 Nevada law units. Ms. Miller is the Dean of Everest College and she and a registered Pharmaceutical Technician will be teaching the program. It was noted that they do not have a pharmacist on the faculty.

Keith Macdonald noted that the Board has had bad experiences with pharmaceutical technician training programs. The students spend a lot of money for a level of training that is lacking. Mr. Macdonald advised that after the students complete these technician training programs they do not know anything and have to rely on their employers to train them. Mr. Macdonald expressed concern for substance of the program. When asked, Ms. Miller indicated that registration in the pharmaceutical technician program at Everest College will be \$10,000.

It was determined to form a committee to establish standards for PT programs. Larry Pinson, Ray Seidlinger, Renee Coffman, and a representative for NACDS will comprise the committee.

Ms. Miller and Mr. Smith were advised that the committee will determine the standard for PT programs and to re-appear after the committee came to a determination.

6. Requested Appearance:

EmployACT, Inc. – Samuel Anderson

Samuel Anderson appeared before the Board and advised them that he had a software product that tracks the precursors to methamphetamine. He described the benefits of being able to track the quantity of ephedrine and pseudoephedrine that is sold at specific stores in single sales.



7. General Counsel Report:

Mr. Ling advised the Board that Bill Drafts are due to LCB by May 1<sup>st</sup>. This topic will be on the April agenda and he asked the Board to think if there is anything they want Board staff to address for the next legislative session.

A. Litigation Update

Dutchess changed the agreement at the last minute and it looks like the parties are going to the Supreme Court. In the meantime, Board staff is seeking collections.

FMC Puerto Rico argued before Judge Adair and she has not made a finding. Mr. Ling advised the Board that she had filed a minute order vacating the fines and attorney fees. He said he would have to wait to see the Order before he could report more.

Joe Kellogg noted that he was present in Judge Adair's courtroom when the FMC Puerto Rico matter was addressed and praised Mr. Ling for a job well done before the judge.

President Kellogg also reported that he attended the Governor's pandemic conference for Larry Pinson.

B. Contracts Update

8. Executive Secretary Report:

A. Financial Report

B. Investment Report

Leo Basch, Board treasurer, reported that he spent the day at the Board office reviewing financial procedures with Larry Pinson and Lisa Hedaria. Mr. Basch reported, in Mr. Pinson's absence, that it looked like the budget was in line.

C. Pending Policy Questions

Mr. Pinson updated the Board on the process of seeking a new licensing program vendor. Staff submitted a proposal to Do It for consideration and they presented six or seven other vendors that have licensing programs. Now we are in the process of researching the other companies and doing RFP's.

All contracts have been updated and have been presented to the Board of Examiners for approval.

Mr. Pinson announced that the Task Force office is moving to Carson City. The Reno office was becoming crowded and this move would alleviate that issue. The cost will be

the same and it will allow us to get rid of the storage facility we rent. Louis Ling will move into the space vacated by the Task Force, Joe Depczynski will move into Mr. Ling's office and the space where Mr. Depczynski currently has his desk will be closed and made into a storage area that will contain the boxes currently housed in the storage facility.

Joe Depczynski attended the Nevada Prepares meeting regarding the bird flu pandemic.

Larry Pinson attended the Legislative Committee Health Care Review and also the CPHA meeting. He addressed the licensing issue previously discussed regarding keeping California pharmacists licensed in Nevada. Mr. Pinson reported that after a mailing to those pharmacists dually licensed in California and Nevada that did not renew their licenses, one hundred have since renewed their licenses after January 2006.

A question came to Board staff regarding radiological technicians administering medications. After discussion Board staff was directed to write regulations to accommodate that practice.

Mr. Pinson reported on the reciprocity survey he took. He said that California now reciprocates with 28 states.

Mr. Pinson learned that disciplined CVS pharmacies in Massachusetts are using the ISMP program.

#### D. Temporary Licenses

Larry Pinson reported that he granted one temporary license since the last Board meeting.

#### E. Bill Drafts Due

Mr. Pinson advised the Board that the deadline for submitting bill drafts for legislative consideration is May 1<sup>st</sup>. He asked them to think if they had any topics they would like Board staff to address and bring them to the April Board meeting for discussion.

#### F. NABP Task Force/Committee Volunteers

Larry Pinson requested volunteers for NABP committees. He asked that anyone that volunteers provide a letter of intent and a resume or vitae no later than May 26, 2006.

### WORKSHOP

9. **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 Nevada Administrative Code 639.NEW** Conditions for a pharmacist declining to fill a prescription.

The Board discussed various reasons this regulation is important including fraudulent prescriptions. If the opposition to this regulation amendment had their way that pharmacists had to fill all prescriptions it would include fraudulent prescriptions. Leo Basch noted that the actual hard copy prescription legally belongs to the patient. Mr. Basch works graveyard shift and if he has any question about a prescription he makes a copy of it and the patient's identification and contacts the physician during business hours, however if the patient demands the prescription back he has to give it to him. He suggested that if you can not verify a prescription perhaps a list of options could be included in this language.

President Kellogg opened the Workshop.

Larry Mathias, representing the Nevada State Medical Association, agreed with contacting the physician if there was any question regarding a prescription being presented to a pharmacist whether it was a question of the prescription being fraudulent or dosage or anything else.

Jenner Taro, representing himself, advised that he felt this language should encompass all drugs and not specifically the morning after pill. Mr. Taro was advised that this language is not drug specific.

Allison Golden of Planned Parenthood made suggested language changes.

Lisa Lynn Chapman stated that she thought the language as written was overbroad and suggested language.

Paige Thies of the ACLU considered the language as written unduly lenient and suggested language.

Harry Gammy suggested the Board look at what would be best for the patient.

President Kellogg closed the Workshop.

After discussion President Kellogg asked for direction for Board staff.

Board Action:

Motion: Keith Macdonald moved to move forward to Public Hearing without change.

Second: Dave Wuest

Action: Passed With One Negative Vote

2. **Amendment of Nevada Administrative Code 639.NEW Compounding.**  
Preparation of sterile and non-sterile compounded prescription drugs.

The Board discussed the language presented and Keith Macdonald, Katie Craven and Dave Wuest addressed specific sections that needed clarification.

President Kellogg opened the Workshop.

Cookie Quandt, representing Longs, asked if the language in 14(2) needed to be a log book or if the documentation could be written on the back of the prescription. After discussion the language would be changed to “make a record.”

David Vasenden of Don’s Pharmacy, questioned the USP only drugs and noted that there are things used in compounding that are not USP drugs. Mr. Vasenden suggested a list of certain products be included.

Laura Carpenter, counsel for Kronos, presented a handout with suggested language changes for the Board to reference.

Brant Skanson of Incline Village Pharmacy suggested language to include chart orders in addition to prescriptions.

President Kellogg closed the Workshop.

After discussion, the Board directed staff to move forward with the process and bring to Public Hearing.

3. **Amendment of Nevada Administrative Code 639.7102 E-Prescribing.**  
Addressing security requirements for approved e-prescribing systems.

Discussion ensued regarding the reality of compliance with the security requirements even after the Board loosened the language. A time-out system, like the Pyxis machines, was also discussed.

President Kellogg opened the Workshop.

There were no public comments.

President Kellogg closed the Workshop.

Board Action:

Motion: Dave Wuest moved to move forward with the process and bring to Public Hearing.

Second: Keith Macdonald

Action: Passed Unanimously

4. **Amendment of Nevada Administrative Code 639.650 Retail Sale of Veterinary Drugs.** New class of registration for feed stores and others who sell veterinary drugs at retail.

This regulation amendment will require feed stores to license with the Board of Pharmacy so records will be maintained and the Board can track the sale of veterinary drugs. Records of drug sales will ensure that prescription only veterinary drugs are actually dispensed by prescription and not just purchased. It was also noted that NRS 639.2345 requires the Board to license all stores that carry veterinary drugs.

It was determined that a call to the Veterinary Board would be appropriate.

President Kellogg opened the Workshop.

There were no public comments.

President Kellogg closed the Workshop.

Board Action:

Motion: Keith moved to move forward with the process and bring to Public Hearing.

Second: Leo Basch

Action: Passed Unanimously

5. **Amendment of Nevada Administrative Code 639.NEW** Licensure of Canadian pharmacies to serve Nevada as out-of-state mail-order pharmacies.

Larry Pinson reviewed the current status of these regulations and reiterated that patient safety is Board staff's primary concern. Mr. Pinson introduced Dawn Polley from Granville Pharmacy, Fabina Kara and David McKay of Canada Way Drugs and acknowledged Assemblywoman Barbara Buckley who was present to observe.

Louis Ling described that the language presented was derived from Board input, legislative intent and input from the public. Mr. Ling reviewed each section noting specifics that licensure of Canadian mail-order pharmacies would have to adhere to in order for them to ship medications into Nevada. Mr. Ling also stressed that patient safety was of the utmost importance. One provision of the language is that if the Canadian pharmacy cannot fill a prescription, it will not be allowed to send the

prescription to an off-shore affiliate. Records will need to be maintained by the pharmacist and pharmacy so when the Board inspector inspects the pharmacy there will be accountability.

The Board discussed the language and made suggestions to Mr. Ling for incorporation into the present draft.

President Kellogg opened the Workshop to the public.

Shirley Swafford appeared and asked if contacts for the Canadian pharmacies would be found through the Attorney General's office for consumer notification. She was advised that the public would go through the Office of Consumer Affairs.

Assemblywoman Barbara Buckley appeared and noted that many groups were present to support the Board's efforts, including the Nevada State Medical Association, AARP and veterans groups. Ms. Buckley affirmed that it was a disgrace for Nevada citizens to have to go to Canada to receive safe, affordable drugs.

Chuck Folkerson appeared and thanked the Board for working with Ms. Buckley and moving ahead on this important regulation. He stated that there were 250,000 veterans in Nevada and found it surprising that there is even an issue with this process and asked how many of the Board members drove foreign cars.

Harry Gammy, a retired social worker, appeared and indicated that he hoped there would not be undue restraints placed on Canadian pharmacies to provide Nevada citizens with affordable Canadian drugs.

Scott Watts thanked the Board for their consideration of this regulation process.

Mary Staples of NACDS reported that she and her group were concerned with patient safety and oppose this illegal and unsafe practice. Ms. Staples noted that she and NACDS support George Chanos' opinion regarding importation of drugs into the United States.

Liz Macmenamin, representing RAN, advised the Board that she and her group oppose importation of Canadian drugs and have opposed this issue since it was proposed at the legislature. She asked how discipline would be handled and was advised it would be the same as any out-of-state pharmacies are currently handled. Ms. Macmenamin wanted to know how inspections were to be handled and was advised that those pharmacies would be inspected annually by our inspector, just like all pharmacies in Nevada.

Charles Sass appeared and asked what the pharmaceutical technician ratio would be. Mr. Sass was advised that each province will operate as individual out-of-state pharmacies operate in the United States. They operate according to each states own laws. Fabina Kara of Canada Way Drugs advised Mr. Sass that some provinces have a

two to one ratio just like in the Nevada and the counseling laws are more stringent than in Nevada.

Susan Fisher of Astra Zeneca asked when these proposed regulations would become effective and was told the earliest would be late April or early May.

Cookie Quandt, representing herself, asked about controlled substances, different names, labeling, counseling and how patients will be protected if their drugs are seized by the FDA. Ms. Quandt's questions were all answered to her satisfaction. It was noted that there will be no controlled substances allowed in this concept.

President Kellogg closed the Workshop.

After discussion, President Kellogg asked for direction for Board staff.

Board Action:

Motion: Keith Macdonald moved to move forward to Public Hearing

Second: Ann Peterson

Action: There were three votes for the motion and three votes against the motion and President Kellogg broke the tie vote by voting for the motion passing it 4 to 3.

6. **Amendment of Nevada Administrative Code 639.725** Allows non-pharmacists to stock automated dispensing devices.

Leo Basch suggested that the new language allowing non-pharmacist personnel to fill automated dispensing devices and exclude the requirement for a pharmacist to check. After discussion the Board determined they would hold off on making that determination at this time. Mr. Basch made other suggestions to clarify the language.

President Kellogg opened the Workshop.

There were no public comments.

President Kellogg closed the Workshop.

Board staff was directed to move forward with the process with the clarification suggested and bring this language to Public Hearing.

7. **Amendment of Nevada Administrative Code 639.NEW** Conditions of repackaging of dispensed prescriptions.

Louis Ling reminded the Board that this regulation amendment almost passed at Public Hearing some time ago. Two different groups appeared and made pleas to consider the impact on assisted living facilities. Pharmacists generally do not like repackaging as it is not cost effective. A committee was formed and this language was created. Liability of repackaging to the repackaging pharmacy is at issue.

President Kellogg opened the Workshop.

Barry Boudreaux of Medco Health Solutions acknowledged that there are repackaging pharmacies that remove the original label and put it on the repackaged medications. Mr. Boudreaux stated that he would not want to be responsible for the repackaged product.

It was noted that labeling needs to be addressed in the language. Patient care in long term care facilities was also discussed and they want Bingo cards.

President Kellogg closed the Workshop.

Board staff was directed to make changes to the current language and bring back to Workshop in April.

## PUBLIC HEARING

10. Notice of Intent to Act Upon a Regulation:

1. **Amendment of Nevada Administrative Code NAC 639.220 Schedule of fees; penalties; applicability.** This will remove the financial burden to physicians that provide health care to underserved persons by allowing them to pay for one registration and change the address to another non-profit facility without providing a fee each time they move to a different location to provide health care to other underserved persons.

President Kellogg opened the Public Hearing.

There was no public comment.

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

### Board Action:

Motion: Keith Macdonald moved to adopt this regulation amendment without change.

Second: Katie Craven

Action: Passed Unanimously



## **2. Amendment of Nevada Administrative Code NAC 639.593 Licensing**

This language implements SB37, the wholesaler statute that was passed this last legislative session.

Louis Ling described that this language is the mechanical implementation of SB 37. If the wholesaler is licensed in another state and in good standing the Nevada Board will allow them to obtain a provisional license until we get their fingerprint report back. Intracompany transfers are not considered a wholesaler transaction and will not need a pedigree. Bonding requirements of \$100,000 for large wholesalers will only be required once and not at each location. Third party logistics wholesalers are really functioning as warehousemen. If publicly traded companies, they do not have to provide fingerprints for renewals. As the language stands now, the pedigree requirements will be implemented on January 1, 2007. They will be required to download pedigree information and report to the Board in the same manner as the Task Force. Board staff is hosting a committee meeting on March 23<sup>rd</sup> and have wholesalers and manufacturers from all over the country attending to help Board staff get a realistic date to implement electronic pedigree and RFID requirements. A letter from the Legislative Counsel Bureau will be incorporated into this regulation to exempt publicly traded companies.

President Kellogg opened the Public Hearing.

Mary Staples, NACDS, Heather Zenk, Walgreens and Cookie Quandt, Longs, appeared and were sworn by President Kellogg prior to answering questions or offering testimony.

Mary Staples stated that she did not have the current language for the Wholesaler regulations. It was explained that the Legislative Counsel Bureau does not always provide their language before the 30-day posting requirements, and so Board staff posts what was in the Board book. It has never been Board staff's procedure to re-mail the language sent by LCB when it was received as sometimes it is not received until the day before a Board meeting, however Board staff will try to communicate better with NACDS.

Heather Zenk noted that "ongoing relationship" is not defined. Mr. Ling advised Ms. Zenk that we have changed that because there are no longer two sales within 24 months. Now the requirement is to provide pedigrees.

Cookie Quandt questioned the required bond. Would current wholesalers need to provide a bond or would it just be for new wholesalers and she was advised that it was for everyone. Ms. Quandt asked whether returns to a reverse distributor is allowed in this process. Mr. Ling advised that it is not addressed specifically in this language, however it does not allow for returns to an outside distributor.

Colleen Chawla appeared and was sworn by President Kellogg prior to answering questions or offering testimony.

Ms. Chawla asked if publicly traded manufacturer/wholesaler for Flumist would be exempted. Mr. Ling advised that they would be exempt from the bond and the fingerprints.

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

Board Action:

Motion: Leo Basch moved to adopt as presented.

Second: Ann Peterson

Action: Passed Unanimously

3. **Amendment of Nevada Administrative Code NAC 639.945 Unprofessional conduct; owner responsible for acts of employees.** This language will include "chart orders" to be added to the unprofessional conduct regulations used in charging hospitals disciplinary matters.

President Kellogg opened the Public Hearing.

There were no comments.

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

Board Action:

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

Second: Katie Craven

Action: Passed Unanimously

11. Next Board Meeting:

April 19 & 20, 2006 – Las Vegas, Nevada

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

There were no public comments.