May 20, 2009

#### **AGENDA**

#### ♦ PUBLIC NOTICE ♦

#### NEVADA STATE BOARD OF PHARMACY

**BOARD MEETING** 

at the

Airport Plaza Hotel 1981 Terminal Way Reno

Wednesday, June 3, 2009 – 9:00 am

Thursday, June 4, 2009 – 9:00 am

<u>Please Note:</u> 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.

#### June 2009 Board Meeting Agenda

- \* 1. Approval of April 15, 2009, Minutes
- \* 2. Applications for Out-of-State MDEG Non Appearance:
  - A. American Diabetes Wholesale, LLC Pompano Beach, FL
  - B. Atos Medical, Inc. West Allis, WI
  - C. Avnet, Inc. Chandler, AZ
  - D. Destiny Medical Supply, Inc. Aurora, CO
  - E. Diabetes Care Club, LLC Brentwood, TN
  - F. Kolob Oxygen + Medical Equipment St. George, UT
  - G. Optigen Inc. Jacksonville Beach, FL
  - H. Total eMedical, Inc. Pompano Beach, FL
  - I. Walgreen Medical Supply, LLC Tinley Park, IL
  - J, Wilmington Medical Supply, Inc. Wilmington, NC

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

- K. Apothecary Shop of Scottsdale Scottsdale, AZ
- L. Apothecary Shop of Tucson Tucson, AZ
- M. Axelacare Health Solutions LLC Lenexa, KS
- N. Benecard Central Fill Mechanicsburg, PA
- O. Mayo Clinic Pharmacy Rochester, MN
- P. Meds for Vets Sandy, UT
- Q. San Ysidoro Pharmacy Santa Barbara, CA
- R. Specialty Compounding, LLC Cedar Park, TX

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

- S. Abbott Laboratories, Inc. Fontana, CA
- T. Ace Surgical Supply Co., Inc. Brockton, MA
- U. Bryant Ranch Prepack North Hollywood, CA
- V. Cardinal Health St Charles, MO
- W. DSC Logistics, Inc. Roanoke, TX
- X. Sanvita, Inc. Tampa, FL
- Y. Septodont, Inc. New Castle, DE

#### Application for Nevada MDEG – Non Appearance:

Z. Airgas, Northern California & Nevada – Winnemucca, NV

Applications for Nevada Pharmacy – Non Appearance:

- AA. Center for Surgical Intervention, LLC Las Vegas
- BB. Solutions II LTC Henderson
- CC. Target Pharmacy T-2569 Las Vegas

#### ♦ REGULAR AGENDA ♦

- \* 3. Applications for Out-of-State Pharmacy Appearance
  - A. College Pharmacy Colorado Springs, CO
  - B. Med Shop Total Care Longview, TX
- \* 4. Disciplinary Action: <u>Note</u> 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. Walgreens #05295 (08-076-PH-N)
B. Smith's Pharmacy #392 (08-070-PH-N)

\* 5. Requests for Reinstatement – Appearance:

Henry A. Miller (08-006-RPH-S)

- \* 6. General Counsel Report
- \* 7. Executive Secretary Report:
  - A. Financial Report
  - B. Investment Report
  - C. Temporary Licenses
  - D. Staff Activities
    - 1. Meetings
      - a. PT Committee (4/22)
      - b. Telepharmacy/Telemedicine (4/23 & 4/28)
      - c. NABP Miami
    - 2. Legislative Update
      - a. Hillerby Report
  - E. Reports to Board
    - 1. Abuse of Emergency CII Rx Rule
    - 2. Ryan Haight Act
    - 3. Virginia PMP Hack
    - 4. Tech School Requirements
    - 5. Temporary Regulations
  - F. Board Related News
  - G. Activities Report
- \* 8. Personnel Review 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. Personnel Evaluation and Salary Review
  - B. Executive Secretary Evaluation

June 2009 Board Meeting Agenda

\* 9. Review and Approval of 2010 Board Meeting Dates

### W O R K S H O P – Thursday, June 4, 2009 – 9:00 am

- \*10. **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 639.707** Counseling of Patients: Duties of pharmacist or intern pharmacist; documentation.
  - 2. **Amendment of Nevada Administrative Code 639.7125** Use of fulfillment pharmacy by dispensing pharmacy.
  - 3. **Amendment of Nevada Administrative Code 639.694** MDEG Administrator required.
  - Amendment of Nevada Administrative Code 639.725 Use of mechanical counting devise for dispensing medications to be taken orally.
  - 5. **Amendment of Nevada Administrative Code 639.528** Preparation and storage of food in prescription department of pharmacy.
- 11. Next Board Meeting:

July 15-16, 2009 - Las Vegas

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

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.

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, 431 W Plumb Lane, Reno, Nevada 89509, 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.

June 2009 Board Meeting Agenda

Continuing Education credit of 4 hours, including 1 hour of law, will be given per day of Board meeting attendance. You are required to attend the board meeting for a <u>full day</u> to receive CE credit including the law credit.

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



# Nevada State Board of Pharmacy

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

#### **BOARD MEETING**

at the

Las Vegas Chamber of Commerce 6671 Las Vegas Blvd South Las Vegas

Wednesday, April 15, 2009

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

#### **Board Members Present:**

Keith Macdonald

Leo Basch

David Chan

Donald Fey Mary Lau Chad Luebke

Kam Gandhi

Board Members Absent:

### **Board Staff Present:**

Larry Pinson

Jeri Walter

Carolyn Cramer

Suzanne Warren

### **CONSENT AGENDA**

- 1. Approval of March 4-5, 2009, Minutes
- 2. Applications for Out-of-State MDEG Non Appearance:
  - A. Cypress Medical Products LLC Elwood, IL
  - B. Medical Care Club, LLC Brentwood, TN

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

- C. Allergychoices Pharmacy La Crosse, Wi
- D. Apothecary Shop of Chandler Phoenix, AZ
- E. Apothecary Shop of Deer Valley Phoenix, AZ
- F. Belmar Pharmacy Lakewood, CO
- G. Costa Mesa Compounding Pharmacy Costa Mesa, CA
- H. Embrace Pharmacy Appleton, WI
- I. Healthwarehouse.com, Inc. Cincinnati, OH

- J. HPC, LLC Mobile, AL
- K. KG Pharmacy Los Angeles, CA
- L. K Mart Pharmacy #9074 Sheridan, WY
- M. Omnicare Clinical Intervention Center-NW Ohio Maumee, OH
- N. Omnicare Pharmacy of Florida, LP Longwood, FL
- O. Pharmacy Incorporated Murray, KY
- P. Rx Stat, Inc. St. Petersburg, FL
- Q. Talon Compounding Pharmacy San Antonio, TX
- R. WellDyneRx-FL Lakeland, FL

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

- S. Arrow International, Inc. Asheboro, NC
- T. Bedford Laboratories A Div-of Ben Venue Laboratories Walton Hills, OH
- U. Blu Pharmaceuticals Franklin, KY
- V. Cypress Pharmaceutical, Inc./Hawthorn Pharmaceuticals Madison, MS
- W. Grifols Biologicals, Inc. City of Industry, CA
- X. McKesson Drug Company Aurora, CO
- Y. McKesson Drug Company Rocky Hill, CT
- Patterson Dental Supply, Inc. Salt Lake City, UT
- AA. RxElite Holdings, Inc. Mountain Home, ID
- BB. Teleflex Medical Incorporated Durham, NC
- CC. Teleflex Medical Incorporated Fort Worth, TX
- DD. UDL Laboratories, Inc. Rockford, IL

Application for Nevada MDEG – Non Appearance:

EE. Hill-Rom – Sparks

Applications for Nevada Pharmacy – Non Appearance:

- FF. Specialty Surgery Center of Pecos Las Vegas
- GG. Walgreens #11226 Reno

## Discussion:

The consent agenda applications and supporting documents were reviewed.

NOTE: Leo Basch recused from participation in the vote on item GG as he is employed by Walgreens. Mary Lau recused from participation in the vote on items GG and L as Walgreens and K Mart are members of the Retail Association of Nevada.

### **Board Action:**

Motion: Keith Macdonald found the consent agenda application information to be

accurate and complete and moved for approval with the exception of

items GG and L.

Second: Leo Basch

Action: Passed Unanimously.

Motion: Keith Macdonald moved for approval of items GG and L.

Second: Chad Luebke

Action: Passed Unanimously.

#### Discussion:

Mary Lau noted that reference to Senator's Carpenter and Denis needed to be changed to Assemblymen. Mr. Pinson indicated that had already been corrected.

Leo Basch indicated that item 6B needed clarification that veterinarians that would be working under another veterinarian's DEA license and controlled substance registration would only need their own DEA license and controlled substance registration if they would be giving prescriptions to a client to be filled elsewhere.

Motion: Leo Basch found the minutes to accurate and complete and moved for

approval with the referenced changes.

Second: Keith Macdonald

Action: Passed Unanimously.

#### REGULAR AGENDA

3. Application for Nevada Pharmacy – Appearance:

Central Admixture Pharmacy Services, Inc. – Las Vegas

Michael Koch appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Koch explained that Central Admixture Pharmacy Services (CAPS) is an IV outsourcing company. He explained how the company operated and who they sold to. The letter Board staff received from Bill Jones was unclear regarding their status with the FDA and they asked Mr. Koch to explain their association. The Board explained that any product shipped into Nevada had to be patient specific and that they could not ship bulk quantities to a location for use as needed by a facility without being licensed

as a manufacturer. After further discussion, Mr. Koch indicated that he would abide by Nevada's rules and perhaps at a later time would pursue the possibility of becoming a manufacturer.

#### **Board Action:**

Motion: Keith Macdonald moved to accept the application for Nevada pharmacy

from CAPS providing they do patient specific compounding.

Second: Leo Basch

Action: Passed Unanimously

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

A. ApotheCure, Inc. – Dallas, TX

Gary Osborn appeared and was sworn by President Fey prior to answering questions or offering testimony.

Brent Cooper, Mr. Osborn's attorney appeared to represent him and help answer questions.

It was noted that this application was originally received in the Board office on November 3, 2007 and is one and one half years old. Applicants would normally need to re-apply if they couldn't license within one year. When ApotheCure first applied to the Nevada Board of Pharmacy they advised that they had a license denied by the Indiana Board of Pharmacy due to a death that occurred in Oregon from an unsafe batch of colchicine. The Texas Board of Pharmacy had ApotheCure under investigation concerning the colchicine matter. The Board initially told Mr. Osborn that he needed to handle the incidents in the other states before Nevada would consider his application for an out of state pharmacy. To date these matters have not been resolved.

Mr. Osborn explained to the Board the steps they have taken to resolve this issue. Mr. Cooper noted that they were still honing the fine details of an agreement and it should be resolved shortly. President Fey asked Mr. Cooper specifically how long it would be before the negotiations would be complete and asked if it could be completed by July, our next Board meeting in Las Vegas. Mr. Cooper indicated that would not be a problem.

Mr. Osborn and Mr. Cooper were advised that they would have to abide by Nevada's rules and their products would need to be patient specific and sold directly to the patient, not the doctor or through the doctor's office and they cannot provide their products to a physician for general use. Mr. Osborn indicated that he understood.

#### **Board Action:**

Motion: Keith Macdonald moved to table this application until the July Board

meeting.

Second: Chad Luebke

Action: Passed Unanimously

B. DrugCrafters – Frisco, TX

Giueseppe (Joe) Gallucci appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Gallucci testified that DrugCrafters was a compounding pharmacy that provided injectables to homeopathic doctors. He indicated that he had contracts with doctors in Nevada and has been shipping to them for some time. He stated that he worked for ApotheCure and was just doing the same thing at DrugCrafters that he was doing at ApotheCure. Mr. Gallucci indicated that he was licensed in California, Arkansas, Louisiana and Oklahoma and he obtained licenses with their Board's of Pharmacy after he began shipping into the state not knowing if it is a requirement to be licensed.

After Mr. Gallucci's testimony regarding his business practice the Board found it would be difficult at best for Mr. Gallucci to ship his products to be patient specific and follow Nevada's laws.

#### **Board Action:**

Motion: Mary Lau moved to deny the application for out of state pharmacy for

DrugCrafters.

Second: Leo Basch

Action: Passed Unanimously

5. Applications for Nevada MDEG – Appearance:

A. APM Medical Suppliers – Las Vegas

Marcel Chatal appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Chatal was questioned regarding his qualifications to be the facility administrator for APM Medical Suppliers. Mr. Chatal explained that he bought into the company as the owners are planning ahead for retirement. This was not a change in ownership, he is now one third owner along with the existing owners. Mr. Chatal explained that he was a

nurse in Sweden however he had not pursued that status in the United States. He was advised that he needed to be properly trained to sell medical devices in Nevada. The Board asked Mr. Chatal if the other two persons were still going to stay on in the business at APM Medical Suppliers and would train him appropriately to ultimately become the facility manager. Mr. Chatal stated nothing has changed, that he was just joining the current owners.

Mr. Chatal was advised that Board staff could have approved this application without being brought to the Board for hearing. It is a requirement to notify the Board if there is a change in the facility administrator. The Board suggested that the current facility manager, Mr. Malito, train Mr. Chatel, then apply to the Board for a change in facility administrator with a letter outlining Mr. Chatel's training and readiness.

### B. Caring Medical Supply, LLC – Henderson

Norman Hicks and Michael Barbara appeared and were sworn by President Fey prior to answering questions or offering testimony.

Board staff advised that this is a new application. They had applied in January and withdrew their application because of pending litigation.

Mr. Hicks indicated that the litigation is still pending but is close to resolution. President Fey asked if they would have their issues resolved by the July Board meeting and they agreed that would be ample time.

#### **Board Action:**

Motion: Keith Macdonald moved to table the application for Caring Medical Supply

until the July Board meeting.

Second: Kam Gandhi

Action: Passed Unanimously

C. Gabel Distributors, LLC - Las Vegas

Andy Gable appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Gable described his business and his products. He provides passive motion machines to patients for post op therapy for wrists, knees, elbows, shoulders, ankles, or any part of the body that needs physical therapy. Mr. Gable reviewed his procedures regarding his interaction with patients and physicians and how he works with them to meet their needs. Mr. Gable admitted during testimony that he is already conducting business in Nevada even though unlicensed.

#### **Board Action:**

Motion:

Keith Macdonald moved to approve the application for Gable Distributors.

Second:

Leo Basch

Action:

**Passed Unanimously** 

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

C.T. International – San Luis Obispo, CA

Michael Kyle appeared and was sworn by President Fey prior to answering questions or offering testimony.

CT International has been in operation for 21 years and are licensed in every state in the United States. They had a license in Nevada previously but were not using it and let it lapse. In California they had discipline and President Fey asked Mr. Kyle to explain the circumstances. Mr. Kyle explained that they had opened a compounding pharmacy within their wholesaler location. In California that was acceptable, but there were timeframes and procedures that were not being adhered to. In the meantime, California required that a compounding pharmacy had to comply with sterile compounding requirements. CT International was inspected and it was found that they were not compliant when transferring products from the wholesale facility to the pharmacy and vice versa. After that incident and the requirement for them to convert their compounding pharmacy to a sterile compounding pharmacy they determined to close the pharmacy and not compound product any longer and just operate their wholesaler facility.

#### **Board Action:**

Motion:

Leo Basch moved to accept the application for CT International.

Second:

Keith Macdonald

Action:

Passed Unanimously

7. Disciplinary Action:

Terrance L. Rogers, R.Ph

(09-014-RPH-S)

Carolyn Cramer noted that Mr. Rogers was not present for hearing even though he received notice.

NOTE: Leo Basch recused from participation in this matter as he is employed by Walgreens, as was Mr. Rogers. Mary Lau disclosed that Walgreens is a member of RAN however it would not affect her participation in this matter.

Mary Curran, loss prevention supervisor for Walgreens, appeared and was sworn by President Fey prior to answering questions or offering testimony.

Ms. Cramer asked Ms. Curran to explain her job duties and how she became involved in this matter.

Ms. Curran testified that her investigation came as the result of a complaint by a Walgreens patient. The patient requested a patient profile on herself for her insurance company and found that many of the prescriptions that were attributed to her were not actually hers. Ms. Curran testified that Terrance Rogers was the person that processed all of the prescriptions and it was found that he did not scan them. He filled the prescriptions without a prescription to authorize the fills. Ms. Curran talked to Mr. Rogers and he indicated that all the prescriptions he filled were refills but Ms. Curran could not locate any hard copy prescriptions in the files to authenticate Mr. Rogers's story. Ms. Curran stated that there were fifteen prescriptions that could not be accounted for and the medications that were filled were hydrocodone, Alprazolam, Oxycodone and carisoprodol. Mr. Rogers did not admit to obtaining those prescriptions for his personal use, only to taking hydromorphone and morphine sulphate when he would forget to bring his own medication to work. In Mr. Rogers written statement he also indicated that he would return some of the medication from his personal prescriptions at home.

Ms. Cramer reminded the Board that it was illegal to return medications once they leave the pharmacy and that obtaining medication from his employing pharmacy without authorization from a physician is also illegal. Ms. Cramer recommended revocation of Mr. Rogers's pharmacist license.

#### **Board Action:**

Motion: Keith Macdonald moved to find Mr. Rogers guilty of the alleged violations.

Second: Chad Luebke

Action: Passed Unanimously

Motion: Keith Macdonald moved to revoke Mr. Rogers's pharmacist license and

Mr. Rogers will be responsible for the Board's fees and costs in this

matter.

Second: Kam Gandhi

Action: Passed Unanimously

8. Request for Pharmacist License – Reciprocation – Appearance:

Madonna R. Wilcox, R.Ph

Ms. Wilcox cancelled her appearance and will reschedule at a later date.

9. Requests for Reinstatements – Appearance:

A. James Ammon, R.Ph

(08-021-RPH-O)

James Ammon appeared and was sworn by President Fey prior to answering questions or offering testimony.

Carolyn Cramer noted for the Board that when Mr. Ammon renewed his license he did not disclose that he had surrendered his license in another state. President Fey asked Mr. Ammon to explain why he was appearing now to request reinstatement of his pharmacist license at this point in time.

Mr. Ammon stated that he was imprisoned for seven months for pleading guilty to felony healthcare fraud.

Keith Macdonald asked Mr. Ammon if he had cleared up his legal problems. Mr. Ammon testified that he was still on probation until November of 2009. Mr. Macdonald asked if he had reinstated his license with the Utah Board of Pharmacy. Mr. Ammon explained that he was trying to reinstate Utah, Wyoming and Nevada concurrently. Mr. Macdonald explained that it is this Board's practice to have a pharmacist get his business in order with his home state before he requests reinstatement in Nevada and understands that most states generally follow that protocol.

#### **Board Action:**

Motion:

Keith Macdonald moved to have Mr. Ammon clear up his license in Utah

before he requests reinstatement.

Second:

David Chan

Action:

**Passed Unanimously** 

B. Scott James, R.Ph

(06-048-RPH-S)

Mr. James did not appear because he had not complied with his Board Order dated November 21, 2006 which required him to pay a fine of \$2,000.00 plus costs and fees before he requests reinstatement of his pharmacist license.

C. William Tinghitella, PT

(00-063-PT-S)

Mr. Tinghitella cancelled his appearance to request reinstatement of his pharmaceutical technician registration.

D. Robert Carillo, PT

(07-015-PT-S)

Mr. Carillo cancelled his appearance to request reinstatement of his pharmaceutical technician registration and will contact Board staff to reschedule.

10. Request for Appearance:

CVS - Susan DelMonico

Ms. DelMonico cancelled her appearance due to a family emergency.

- 11. Requests for Pharmaceutical Technician in Training License Appearance Required:
  - A. Christopher Bianchi

Christopher Bianchi appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Bianchi appeared before the Board because he tested positive for marijuana during a random drug test at Kaplan College, where he is currently enrolled in their pharmaceutical technician program. Mr. Bianchi needs a pharmaceutical technician in training registration to complete the course.

Mr. Bianchi explained that he used poor judgment when he went out with friends and smoked marijuana. He did this once. He came to Nevada from another state because a family member that lives here suggested there were job opportunities in the casino industry. By the time he moved here the economy was unstable and there wasn't the opportunity there once was. He looked at various opportunities and decided to enroll in the pharmaceutical technician program at Kaplan College.

The Board questioned Mr. Bianchi regarding how long before the drug test he had smoked marijuana and he stated that it was two days before the test. Mr. Bianchi was asked how much money he paid Kaplan College to take their program and Mr. Bianchi indicated that the tuition was \$14,000.00.

#### **Board Action:**

Motion: David Chan moved to approve Mr. Bianchi's application for

pharmaceutical technician in training providing he is evaluated by PRN-

PRN and has a positive result.

Second: Mary Lau

Action: Passed With One Negative Vote

#### B. Ramon A. Dean

Ramon Dean appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Dean answered "yes" to a question on his pharmaceutical technician in training application indicating that he had been charged, arrested or convicted of a misdemeanor. Mr. Dean testified that he had taken his younger brother to a basketball game and his brother was in possession of marijuana. He explained that he took responsibility for his brother's actions and was ticketed for possession of an illegal substance.

The Board questioned Mr. Dean regarding his grades at Kaplan College and he stated he had a 3.8 grade point average and was honored with academic excellence for five months and had a 93% attendance average, He completed his last class on March 13<sup>th</sup> and now needs to do his externship to complete the program, thus, the need for the pharmaceutical technician in training registration. President Fey asked Mr. Dean if this was an expensive program for him and Mr. Dean responded that it was since he was not currently working, however he had applied for a student loan and felt it worthwhile so he would have a career opportunity as a pharmaceutical technician.

#### **Board Action:**

Motion: Keith Macdonald moved to approve Mr. Dean's application for

pharmaceutical technician in training providing he is evaluated by PRN-

PRN and has a positive result.

Second: Kam Gandhi

Action: Passed With One Negative Vote

#### 12. Dutchess Recalculation of Fines

This matter will be addressed at the July Board meeting.

#### 13. General Counsel Report

Carolyn Cramer advised the Board that she has provided a Board book for the public to view during Board meetings beginning with this meeting. Some information on applications has been redacted such as minor children's names, phone numbers and addresses to ensure privacy. If this practice meets with their approval, a Board book will be provided at future meetings. After discussion it was determined that this practice will be implemented.

- 14. Executive Secretary Report:
  - A. Financial Report
  - B. Investment Report

Larry Pinson gave the financial and investment reports to the Board's satisfaction.

C. Temporary Licenses

One temporary license was granted since the last Board meeting.

- D. Staff Activities
  - 1. Meetings
    - a. Fulfillment Committee (3/26)

The committee helped Board staff rewrite the regulations regarding fulfillment pharmacies. They will go back to the committee and may be ready for Workshop in June.

b. Speaking engagements (dental; APhA; Pharm. Conf.)

Mr. Pinson gave details regarding his speaking engagements.

c. Legislative update

Hillerby Report

Fred Hillerby's reports were given to the Board for their information.

d. PT Committee; Telepharmacy

Larry Pinson advised the Board that the PT committee would be meeting on April 22<sup>nd</sup>, 2009 and he would be meeting with a representative from Rural Health regarding Telepharmacy on April 23<sup>rd</sup>, 2009.

- E. Reports to Board
  - 1. NABP Award

NABP is one of only 21 organizations to receive a national Award of Excellence for the 2009 Associations Advance America Awards program which is a national competition sponsored by the American Society of Association Executives and the Center for Association Leadership in Washington DC.

2. Surgery Center Inspections

Mr. Pinson reported that there were only twelve more surgery centers left to inspect from the original fifty. Five in the South and seven in the North. Some of the surgery centers in the North are rural and will be inspected as regular inspections are scheduled for the rural areas. Compliance appears to be good.

- F. Board Related News
- G. Activities Report
- 15 . Next Board Meeting:

June 3-4, 2009 – Reno

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

There were no public comments.

431 W Plumb Lane - Reno, NV 89509 - or (775) 850-1440

## APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG Provider Ownership Change Name Change Location Change   |
|--|
| FACILITY INFORMATION   |
| Facility Name: AMERICAN DIABETES Wholesaue, LLC  |
| Physical Address: 2501 NW 344 PLACE - SUITE 35   |
| Mailing Address: SAME AS PHYSICAL MODILES (ABOUE)  |
| City: POMPANO BEACH State: FL Zip Code: 33069-5928   |
| Telephone Number: 954-975-3787 Fax Number: 954-975-3786  |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING   |
| Mon: $9a \text{ to } 5\rho$ Tue: $9a \text{ to } 5\rho$ Wed: $9a \text{ to } 5\rho$ Thu: $9a \text{ to } 5\rho$                            |
| Fri: 9a to Sp Sat: Croses Sun: Croses Holidays: Croses   |
| FACILITY ADMINISTRATOR INFORMATION   |
| Name: ERIC CHIRIPSKY   |
| Address: 2501 NW 34th Punce  |
| City: YDMPASS BEACH State: Fr. Zip Code: 33069-5928  |
| Telephone Number: 954-975-3787   |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)   |
| Medical Gases Assistive Equipment Respiratory Equipment  |
| Parenteral and Enteral Equipment  — Life-sustaining equipment  Home Blood Gibbose Testino Para To For Pellons with Diagram                 |
| Home BLOOD Glucose TESTING PRODUCTS FOR PERSONS WITH DIABOTED If providing life-sustaining equipment, provide a 24-hour contact number: () |
| Board Use Only   |
| Received APR 29 2000 Check Number 191 Amount 500.00  |
|  |

431 W Plumb Lane - Reno, NV 89509 - or (775) 850-1440

## APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG Provider 🖊 Ownership Change Name Change Location Change             |
|--|
| FACILITY INFORMATION   |
| Facility Name: ATOS Medical, Inc   |
| Physical Address: 11390 W Theodore Trecker way                               |
| Mailing Address:   |
| City: West Allis State: WI Zip Code: 53214                                   |
| Telephone Number: 800 - 217 - 0025 Fax Number: 414 - 765 - 9174              |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING                 |
| Mon: 8 to 5 Tue: 8 to 5 Wed: 8 to 5 Thu: 8 to 5                              |
| Fri: 8 to 5 Sat: — to — Sun: — to — Holidays: — to —                         |
| FACILITY ADMINISTRATOR INFORMATION   |
| Name: <u>Cuben Cardenas</u>  |
| Address: 11390 W Theodore Trecker way  |
| City: West allis State: WI Zip Code: 53214                                   |
| Telephone Number: 414-921-0002   |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)           |
| Medical Gases  |
| If providing life-sustaining equipment, provide a 24-hour contact number: () |
| Board Use Only   |
| Received APR 29 2009 Check Number 744 Amount 500.00                          |

431 W Plumb Lane - Reno, NV 89509 - or (775) 850-1440

## APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG Provider  | xxxx Owner               | ship Change _           | Name (             | Change                 | Location Change       |   |
|--|--------------------------|-------------------------|--------------------|------------------------|-----------------------|---|
| FACILITY INFORM  | ATION                    |                         |                    |                        |                       |   |
| Facility Name:   | Avnet, Inc.              |                         |                    |                        |                       |   |
| Physical Address:  | 6700 S. More             | los Place, Chan         | dler, Arizon       | ıa 85226               |                       |   |
| Mailing Address:   | Avnet, Inc.,             | Attn: Daniel            | Friedman, 87       | 00 S. Price            | Road                  |   |
| City:  | Tempe                    | State:                  | Arizona            | _ Zip Code:            | 85284                 |   |
| Telephone Number:  |                          |                         |                    |                        |                       |   |
| DAYS AND HOURS   | THAT THE                 | ACILITY WILL            | BE REGU            | LARLY OPE              | RATING                |   |
| Mon: 8am to 5pm  | Tue: 8am to              | <sup>5pm</sup> Wed: _   | 8am to 5pm         | Thu: Sam to            | O 5pm                 |   |
| Fri: 8ato 5pm  | Sat: N/A to              | N/A Sun: N              | I/A to N/A         | Holidays: 1            | N/A to N/A            |   |
| FACILITY ADMINIS   | TRATOR INF               | ORMATION                |                    |                        |                       |   |
| Name: Maureen S  | lagle                    |                         |                    |                        |                       |   |
| Address: Avnet, In   | c. 2211 S. 47            | th Street               | ****               |                        | × *-                  |   |
| City: Phoenix  |                          | State: _                | Arizona            | Zip Code:              | 85034                 |   |
| Telephone Number:  | 480.643.710              | 3                       |                    |                        |                       |   |
| TYPE OF MDEG PR  | ODUCTS TH                | AT WILL BE P            | ROVIDED (          | CHECK ALL              | APPLICABLE)           |   |
| Medical Gases Parenteral and El NOTE: Please see the f providing life-sustai | xxx Ass<br>nteral Equipm | sistive Equipme<br>nent | nt<br>_ Life-susta | Respirate ining equipm | ory Equipment<br>nent |   |
| Board Use Only   |                          |                         |                    |                        |                       | · |
| Received5_   | 18-09                    | Check Numbe             | 577                | Amo                    | unt 500.00            |   |

431 W Plumb Lane - Reno, NV 89509 - or (775) 850-1440

### APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG Provider X Ownership Change Name Change Location Change   |
|--|
| FACILITY INFORMATION   |
| Facility Name: DESTINY MEDICAL SUPPLY INC.  Physical Address: 13721 F. RICE PL. \$\frac{1}{2}\$210                   |
| Physical Address: 13721 F. RSCE PL. \$210  |
| Mailing Address: 13721 E. RSCE PL. * 210   |
| City: <u>Aurora</u> State: <u>CO</u> Zip Code: <u>80015-1062</u>   |
| Telephone Number: 720-870-5330 Fax Number: 720-870-5931  |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING   |
| Mon: 8 Am to SPM Tue: 8 Am to SPM Wed: 8 Am to SPM Thu: 8 Am to SPM  |
| Fri: Santo Sam Sat: CLOSED Sun: CLOSED Holidays: CLOSED  |
| FACILITY ADMINISTRATOR INFORMATION   |
| Name: CRASE A. SMETH   |
| Address: 3953 S. SHAWNEE ST.   |
| City: HURORA State: CO Zip Code: 80018   |
| Telephone Number: 303-699-6120   |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)   |
|  |
| Medical Gases X Assistive Equipment Respiratory Equipment Parenteral and Enteral Equipment Life-sustaining equipment |
| If providing life-sustaining equipment, provide a 24-hour contact number: ()   |
| Board Use Only   |
| Received MAY 0 6 2009 Check Number 151 Amount 500,66   |

431 W Plumb Lane - Reno, NV 89509 - or (775) 850-1440

## APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG Provider X Ownership Change Name Change Location Change                    |
|---|
| FACILITY INFORMATION  |
| Facility Name: Diabetes Care (lub, LLC  |
| Physical Address: 210 Westwood Place, Suite 400 Brentwood, TN 37027                 |
| Mailing Address: Z10 Westwood Place, Suite 400 Brentwood, TN 37027                  |
| City: Brentwood State: TN Zip Code: 37027   |
| Telephone Number: 800 - 883 - 0608 Fax Number: 615 - 866 - 6268                     |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING                        |
| Mon: 7am to 8pm Tue: 7am to 8pm Wed: 7am to 8pm Thu: 7am to 8pm                     |
| Fri: 7am to 8pm Sat: to Sun: to Holidays: to  |
| FACILITY ADMINISTRATOR INFORMATION  |
| Name: Larson Douglas Hudson   |
| Address: 210 Westwood Place, Suite 400  |
| City: Brentwood State: TN Zip Code: 37027   |
| Telephone Number: 800-883-0608  |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)                  |
|   |
| Medical Gases X Assistive Equipment Respiratory Equipment Life-sustaining equipment |
| L Diadets Supplies  |
| If providing life-sustaining equipment, provide a 24-hour contact number: ()        |
| Board Use Only  |
| Received MAY 0 6 ZUU9 Check Number 308 Amount 500.00                                |

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## APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG Provider Ownership Change Name Change Location Change   |
|--|
| FACILITY INFORMATION   |
| Facility Name: KOLOB OXYGEN + MENICAL EQUIPMENT  |
| Physical Address: 530 E. TABERNACLE ST., SAINT GEORGE, UT 84770  |
| Mailing Address: 2600 TECHNOLOGY DR., SUITE 300  |
| City: ORIANDO State: FL Zip Code: 32804  |
| Telephone Number: 435-673-6664 Fax Number: 435-673-0651  |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING   |
| Mon: 8:30 Am 5:00 Tue: 8:38 to 5:00 Wed: 8:30 to 5:00 Thu: 8:30 to 5:00 Pm   |
| Fri: 8:30 to Sat: CLCSED/ON CALL Sun: to Holidays: to  |
| FACILITY ADMINISTRATOR INFORMATION   |
| Name: <u>JOYCE THAYNE</u>  |
| Address: 3849 N. DRIFTWOOD LANE  |
| City: CEDAR CITY State: <u>UT</u> Zip Code: <u>84721</u>   |
| Telephone Number: 4 <u>35-865-5983</u>   |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)   |
| <ul> <li>✓ Medical Gases</li> <li>✓ Assistive Equipment</li> <li>✓ Respiratory Equipment</li> <li>✓ Parenteral and Enteral Equipment</li> <li>✓ Life-sustaining equipment</li> </ul> |
| If providing life-sustaining equipment, provide a 24-hour contact number: (435) 673-666  |
| Board Use Only   |
| Received APR 1 6 2009 Check Number 773 Amount 500.60   |
|  |

431 W Plumb Lane - Reno, NV 89509 - or (775) 850-1440

## **APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION**

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG Provider Ownership Change Name Change Location Change                    |
|---|
| FACILITY INFORMATION  |
| Facility Name: Optigen Inc.   |
| Physical Address: 830 South Third St, Ste 101                                     |
| Mailing Address: (Same)   |
| City: <u>Jacksonville Beach</u> State: <u>FL</u> Zip Code: <u>32250</u>           |
| Telephone Number: 800-273-9114 Fax Number: 877-339-0180                           |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING                      |
| Mon: 9 to 5 Tue: 9 to 5 Wed: 9 to 5 Thu: 9 to 5                                   |
| Fri: 9 to 5 Sat: to Sun: to Holidays: to  |
| FACILITY ADMINISTRATOR INFORMATION  |
| Name: Mark Kennedy  |
| Address: 830 South Third St, Suite 101  |
| City: Tacksonville Beach state: FL zip Code: 32250                                |
| Telephone Number: 800-273-9114  |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)                |
|   |
| Medical Gases Assistive Equipment Respiratory Equipment Life-sustaining equipment |
| If providing life-sustaining equipment, provide a 24-hour contact number: ()      |
| Board Use Only  |
| Received5-19-09   |

431 W Plumb Lane - Reno, NV 89509 - or (775) 850-1440

### APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG Provider X Ownership Change Name Change Location Change  |
|---|
| FACILITY INFORMATION  |
| Facility Name: Total e Medical, Inc.  |
| Physical Address: 3111 SW 10th Street   |
| Mailing Address: 311 SW 10th Stycet   |
| city: Pompand Beach state: FL zip code 33069-4828   |
| Telephone Number: (877) 750-5252 Fax Number: (901) 750-7992   |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING  |
| Mon: $9 to 9$ Tue: $9 to 9$ Wed: $9 to 9$ Thu: $9 to 9$   |
| Mon: $9 to 9$ Tue: $9 to 9$ Wed: $9 to 9$ Thu: $9 to 9$ Fri: $9 to 9$ Sat: $9 to 5$ Sun: $to$ Holidays: $to$        |
| FACILITY ADMINISTRATOR INFORMATION  |
| Name: Gerald Freshman   |
| Address: 6327 San Michel Way  |
| City: Delvau Boh State: FL zip Code: 33484  |
| Telephone Number: 877750-5252_  |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)  |
| Medical GasesX Assistive Equipment Respiratory Equipment Parenteral and Enteral Equipment Life-sustaining equipment |
| If providing life-sustaining equipment, provide a 24-hour contact number: ()  |
| Board Use Only  |
| Received APR 0 8 2009 Check Number 167 Amount 500.00  |

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## **APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION**

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG Provider 🙏 Ownership Change Name Change Location Change   |
|--|
| FACILITY INFORMATION   |
| Facility Name: Walgreen Medical Spply, LLC   |
| Physical Address: 8400 183 <sup>rd</sup> St., Suite F  |
| Mailing Address: 485 Half Dry 2d. Suite 300 Buffalo Grove, 12 60089                                      |
| City: T: Ney Park State: 14 Zip Code: 60487-9373   |
|  |
| Telephone Number: (888) 410 - 5779 Fax Number: (888) 410 - 5780  |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING   |
| Mon: 8 to 6 Tue: 8 to 6 Wed: 8 to 6 Thu: 8 to 6  |
| Fri: 8 to 6 Sat: - to - Sun: - to - Holidays: - to -   |
| FACILITY ADMINISTRATOR INFORMATION   |
| Name: Corky Klobucar   |
| Address: 8402 183 St. Suite F  |
|  |
| City: Tinley Park State: 1L Zip Code: 60487-9373   |
| Telephone Number: (38) 410577)   |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)                                       |
|  |
| Medical GasesX Assistive Equipment Respiratory Equipment Respiratory Equipment Life-sustaining equipment |
| If providing life-sustaining equipment, provide a 24-hour contact number: () UR                          |
| Board Use Only   |
| Received APR 2 9 2009 Check Number 1/30 Amount 500.00  |

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## APPLICATION FOR OUT-OF-STATE MDEG PROVIDER - CORPORATION

FEE: \$500.00 (non-refundable and not transferable) -Application must be printed legibly

| New MDEG ProviderX_ Ownership Change Name Change Location Change  |
|---|
| FACILITY INFORMATION  |
| Facility Name: Wilmington Medical Supply. INC.  |
| Facility Name: Wilmington Medical Supply, Inc.  Physical Address: 2309 S. 17th St., Ste. 200 28401-7901 |
| Mailing Address:PO Box 1594 .28402-1594   |
| City: Wilmington State: NC zip Code: See above  |
| Telephone Number: 910 · 392 · 9553 Fax Number: 910 · 452 - 2913   |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING  |
| Mon: 9A to 5P Tue: 9A to 5P Wed: 9A to 5P Thu: 9A to 5P   |
| Fri: 9A to 5P Sat: N/A to Sun: N/A to Holidays: N/A to  |
| FACILITY ADMINISTRATOR INFORMATION  |
| Name: Martin Gallan   |
| Address: 2309 5. 17th St., Ste. 200   |
| Address: 2309 5.17th St., Ste. 200  City: Wilmington State: NC Zip Code: 28401-7901                     |
| Telephone Number: 910.392.5553  |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)                                      |
| Medical Gases   |
| If providing life-sustaining equipment, provide a 24-hour contact number: ()                            |
| Board Use Only  |
| Received MAY 13 2009 Check Number 5/3 Amount 500.00   |
|   |

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

# APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

| New Pharmacy Ownership Change Name Change Location Change (Please provide current license number if making changes: PHD1784)                |
|---|
| GENERAL INFORMATION   |
|   |
| Pharmacy Name: Potherary SNOP & Scottsdale  |
| Physical Address: 9777 N 918+ 8+ #C-102   |
| Mailing Address: 23420 N 20Th Dv. #12 Phy, AZ 85085   |
| City: Santsola 18 State: AZ Zip Code: 85258   |
| Telephone Number: 480-451-377   Fax Number: 480-451-3503  |
| Toll Free Number: 988-274-8352  |
| E-mail: <u>devans@thearyshop.com</u> website: www.Theapothecaryshop.com   |
| Managing Pharmacist: JUSTIN BYOCK License Number: 3016703   |
| Hours of Operation:   |
| Monday thru Friday \( \frac{1'30}{30} \) am \( \frac{5'30}{2'30} \) pm \qquad Saturday \( \frac{9'30}{30} \) am \( \frac{12'30}{2'30} \) pm |
| Sundayampm 24 Hours   |
| TYPE OF PHARMACY SERVICES PROVIDED  |
| ☐ Retail ☐ Off-site Cognitive Services  |
| ☐ Hospital (# beds) ☐ Parenteral  |
| ☐ Internet ☐ Parenteral (outpatient)  |
| ☐ Nuclear ☐ Outpatient/Discharge  |
| Out of State Mail Service   |
| ☐ Ambulatory Surgery Center ☐ Long Term Care  |
| Board Use Only  |
| Received: MAY 0 6 2009 heck Number: 43 Amount: 500,00   |

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

# APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

| New Pharmacy Ownership Change Name Change Locate (Please provide current license number if making change | tion Change<br>es: PHD 2169) |
|--|------------------------------|
| GENERAL INFORMATION  |                              |
| Pharmacy Name: Apotherary Shop of TUCSON   |                              |
| Physical Address: 4512 6 Lamp Lowell DV.   |                              |
| Mailing Address: 23(230 N 20th DV. #12 Phy AZ 8  | 5085                         |
| City: TUCSON State: AZ Zip Co  |                              |
| Telephone Number: 520-918-5091 Fax Number: 520-915   | 1-0043                       |
| Toll Free Number: 8/16-498-0044  |                              |
| E-mail: devansotheapothecanghop.com Website: www.theapot   | heranyshop.com               |
| Managing Pharmacist: DOUG MOSSUY License Nun   | nber: Solle Ole 7            |
| Hours of Operation:  |                              |
| Monday thru Friday 1:30 am 5:30 pm Saturday  | ampm                         |
| Sundayampm 24 Hours  |                              |
| TYPE OF PHARMACY SERVICES PROVID   | ED                           |
| ☐ Retail ☐ Off-site Cognitive S  | Services                     |
| ☐ Hospital (# beds) ☐ Parenteral   |                              |
| ☐ Internet ☐ Parenteral (outpatie  | ent)                         |
| ☐ Nuclear ☐ Outpatient/Discharg  | ge                           |
| Out of State Mail Service  |                              |
| ☐ Ambulatory Surgery Center ☐ Long Term Care   |                              |
| Board Use Only   |                              |
| Received: MAY 0 6 2009 Check Number: 401 Amount: 50  | 10.00                        |

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431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

| New Pharmacy                       | Ownership Change                     |
|------------------------------------|--------------------------------------|
| GENERAL INFORMATION                |                                      |
| Pharmacy Name: Axela lare Hi       | eglth Solutions LLC                  |
| Physical Address: 9730 Pflum       | om Rd Lenexa KS 66215                |
| Mailing Address: <u>9730 Alumm</u> | pd                                   |
|                                    | State: K5 Zip: 66215                 |
| Telephone Number: 913 310 9119     | Fax Number: 913 310-0682             |
|                                    | E-mail address: Hrammeaxelacore com  |
| •                                  | Cramm License Number: _/-/2006       |
| Hours of Operation:                |                                      |
| Monday thru Friday $8$ am $5^{30}$ | pm Saturday <u>9</u> am <u>/2</u> pm |
| Sunday on Call am                  | pm 24 Hours                          |
| DEA#: FA 0905 705                  | NCPDP#: 1719472                      |
| TYPE OF PHARMACY                   | SERVICES PROVIDED                    |
| Ø Retail                           | ☐ Off-site Cognitive Services        |
| ☐ Hospital (# beds)                | ☐ Parenteral                         |
| ☐ Correctional (# inmates _        | _)                                   |
| ☐ Nuclear                          | ☐ Outpatient/Discharge               |
| Ø Out of State                     | Mail Service                         |
| □ Internet                         | ☐ Long Term Care                     |
| Board Use Only                     |                                      |
| Received MAY 13 2009 Chec          | k Number 484 Amount 500.00           |

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable) Application must be printed legibly

| New Pharmacy $X$ Ownership Change Name Change Lo (Please provide current license number if making cha | ocation Change<br>nges: PH) |
|---|-----------------------------|
| GENERAL INFORMATION   |                             |
| Pharmacy Name: BENECARD CENTRAL FILL  |                             |
| Physical Address: 5040 RITTER ROAD  |                             |
| Mailing Address: 5040 RITTER ROAD   |                             |
| City: MECHANICSBURG State: PA Zip   | Code: 17055                 |
| Telephone Number: 717-458-9100 Fax Number: 717-766  |                             |
| Toll Free Number: 888-907-0090  |                             |
| E-mail: CUSTOMER.SERVICE@BENECARDCF.COM Website: HTTP://www.BEN                                       | NECARDCENTRALFILL.COM       |
| <i>b</i>  | lumber: RP034442L           |
| Hours of Operation:   |                             |
| Monday thru Friday 8:30 am 5:00 pm Saturday   | 8:30 am 5:00 pm             |
| Sundayampm 24 Hours   | NO                          |
| TYPE OF PHARMACY SERVICES PROV  | <u> </u>                    |
| ☐ Retail ☐ Off-site Cognitiv  | ve Services                 |
| ☐ Hospital (# beds) ☐ Parenteral  |                             |
| ☐ Internet ☐ Parenteral (outp   | patient)                    |
| □ Nuclear □ Outpatient/Disch  | harge                       |
| ☐ Out of State ☐ Mail Service   |                             |
| ☐ Ambulatory Surgery Center ☐ Long Term Care  |                             |
| Board Use Only  |                             |
| Received: MAY 13 2009 Check Number: 241 Amount:   | 500.00                      |

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## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

|  | Dwnership Change □ Name Change □ Please provide current license number if making changes: PH |
|--|--|
| GENERAL INFORMATION                    | ¥  |
| Pharmacy Name: Mayo Clinic Pharma      | acy  |
| Physical Address: 21 Second Street S   | W, Brackenridge Building   |
| Mailing Address: Mayo Clinic Pharma    | cy Business Office, 21 2nd St SW, Ste 1-18   |
| City: Rochester                        | State: MN Zip: 55902   |
| Telephone Number: 507-284-2021         | Fax Number: 507-538-1314   |
| Toll Free Number: 1-800-445-6326       |  |
|  |  |
| Managing Pharmacist: Denise Nesbitt    | License Number: 117185   |
| Hours of Operation:                    |  |
| Thurs  Monday thru KKKK 7:00 am 7:00 p | Friday 7:00 am 6:00 pm<br>m Saturday <u>7:00</u> am <u>3:30</u> pm                           |
|  |  |
| Sunday Closed amp                      | m 24 Hours   |
| DEA#: BM0943856                        | NCPDP #: 24-17904  |
| TYPE OF PHARMACY                       | SERVICES PROVIDED  |
| □ Retail                               | ☐ Off-site Cognitive Services  |
| ☐ Hospital (# beds)                    | ☐ Parenteral   |
| ☐ Correctional (# inmates)             | ☐ Parenteral (outpatient)  |
| ☐ Nuclear                              | ☑ Outpatient/Discharge   |
| ☑ Out of State                         | Mail Service   |
| ☐ Internet                             | ☐ Long Term Care   |
| Board Use Only                         |  |
| MAY 1 4 2000                           | Number 938 Amount 500.00   |
| Received WIAT 10 Z000 Check i          | Number 938 Amount 500.33   |

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

# APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)

Application must be printed legibly

| application or subsequent revocation of the license iss | tued and is a violation of the laws of the State of Nevada.              |
|---|--|
| New Pharmacy Ownership Change<br>(Please provide curre  | Name Change Location Change<br>ent license number if making changes: PH) |
| GENERAL INFORMATION                                     |  |
| Pharmacy Name: <u>meds for VETS</u>                     |  |
| Physical Address: <u>585 WEST 940</u>                   | 10 South   |
| Mailing Address: 585 WEST 9400                          | South Ste 100  |
| City: SANDY Sta   | ate: <u>Ufah</u> Zip Code: <u>84070</u>                                  |
| Telephone Number: (801) 255-7666                        | Fax Number: (801) 255- 7690  |
| Toll Free Number: (866) 633 - 4838                      |  |
| E-mail: meds for VETS@gmail. com                        |  |
| Managing Pharmacist: Janice Erickson                    | License Number: 147 149 - 1701   |
| Hours of Operation:                                     | Hours vary by sharmons   |
| Monday thru Friday 8:00 am 5:30 pm                      | Saturday JA auxilability pm  |
| Sunday NN am pm   | 24 Hours <u>W/A</u>  |
| TYPE OF PHARMACY  | SERVICES PROVIDED  |
| ☐ Retail  | ☐ Off-site Cognitive Services  |
| ☐ Hospital (# beds)                                     | ☐ Parenteral   |
| ☐ Internet  | ☐ Parenteral (outpatient)  |
| ☐ Nuclear   | ☐ Outpatient/Discharge   |
| ☑ Out of State  | Mail Service   |
| ☐ Ambulatory Surgery Center                             | ☐ Long Term Care   |
| Board Use Only  |  |
| Received: MAY 0 6 2000 heck Number:                     | 1029 Amount: 500.60  |

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# APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

| New Pharmacy Ownership Change N              | lame Change Location Change<br>ense number if making changes: PH) |
|--|---|
| GENERAL INFORMATION                          |   |
| Pharmacy Name: San Ysidro Pharmacy           |   |
| Physical Address: 1498 East Valley R         |   |
| Mailing Address: 1498 Fast Valley Road Santa | _   |
| City: Santa Barbara State:                   |   |
| Telephone Number: 805 - 969 - 2284 F         |   |
| Toll Free Number: 800 - 796 - 2452           |   |
| E-mail: /hove@aol.com W                      | ebsite: www. San Vsidro pharmacy .com                             |
| Managing Pharmacist: Laymend S. Hoy          | License Number: RPH 39935   |
| Hours of Operation:                          |   |
| Monday thru Friday                           | Saturday <u>IO</u> am <u>3</u> pm                                 |
| Sunday <u>10</u> am <u>2</u> pm              | 24 Hours  |
| TYPE OF PHARMACY                             | SERVICES PROVIDED   |
| ☑ Retail                                     | ☐ Off-site Cognitive Services                                     |
| ☐ Hospital (# beds)                          | ☐ Parenteral  |
| ☐ Internet                                   | □ Parenteral (outpatient)   |
| □ Nuclear                                    | ☐ Outpatient/Discharge  |
| ☑ Out of State                               | ▼ Mail Service  |
| ☐ Ambulatory Surgery Center                  | ☐ Long Term Care  |
| Board Use Only                               |   |
| Received: APR 1 6 2009 Check Number: 7050    | O Amount: _500.00   |

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE PARTNERSHIP

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

| · · · · · · · · · · · · · · · · · · · |   |
|---------------------------------------|---|
|                                       | ne Change Location Change<br>se number if making changes: PH) |
| GENERAL INFORMATION                   |   |
| Pharmacy Name: Specialty Compo        | unding.LLC  |
| Physical Address: 211 5. Bell Blv     |   |
| Mailing Address: 211 S. Bell blv      |   |
| City: Cedar Park State:               | A   |
| Telephone Number: 5/2-219-0724 Fax    |   |
| Toll Free Number: 877-287-8479        |   |
| E-mail: Info DAustin Compounding Web  | m posite: Austra Inmagunding. Com                             |
| Managing Pharmacist: Raymond Soland   |   |
| Hours of Operation:                   |   |
|                                       | 0/ 12   |
| Monday thru Friday 8 am 6 pm          | Saturday 9 am 12 pm   |
| Sunday <u>NH</u> am <u>NA</u> pm      | 24 Hours  |
| TYPE OF PHARMACY                      | SERVICES PROVIDED   |
| ☑ Retail                              | ☐ Off-site Cognitive Services                                 |
| ☐ Hospital (# beds)                   | ☐ Parenteral  |
| □ Internet                            | ☐ Parenteral (outpatient)                                     |
| ☐ Nuclear                             | ☐ Outpatient/Discharge  |
| Out of State                          | ☑ Mail Service  |
| ☐ Ambulatory Surgery Center           | □ Long Term Care  |
| Board Hay Only                        |   |
| Board Use Only                        |   |
| Received: MAY 13 2009Check Number:2   | 34 Amount: _500,00  |

Page 1 - 2009

50294 1490

431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

# APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be typed or printed legibly

| New Wholesaler 🗹 Ownership Change 🗆 Name Change 🗓 (Please provide current license number if making changes: WH                         |
|--|
|  |
| FACILITY INFORMATION  Abbott Laboratories Free.  Weeler Distribution   |
| Facility Name: 10850 Business Drive Fontana, CA 92337  |
| Physical Address:  |
| Abbott Laboratories &  Mailing Address: 100 Abbott Park Rd   |
| City: Zip Code:  |
| Telephone Number: 847-935-9197 Fax Number: 847-937-1708  |
| E-mail: dewise, Stockwarek Capport. Con  |
| Facility Manager: MAUREN BRYSON  |
| Professional qualifications and experience of facility manager: MAJALEW HAS 3 YEARS  |
| EXPERIENCE IN COSTOMER SERVICE 9 YEARS EXPRIENCE IN DISTRIBUTION OPERATIONS.   |
|  |
| Types of licensed outlets or authorized persons firm will serve:   |
| ☐ Pharmacies ☐ Practitioners ☐ Hospitals ☑ Wholesalers ☐ Other ☐ /ᢓŢŢŖ:NARANS  |
| Type of Products to be handled or wholesaled by firm   |
| □ Legend Pharmaceuticals, Supplies or Devices □ Poisons or Chemicals □ Controlled Substances (include copy of DEA certificate) □ Other |
| Board Use Only   |
| Received APR 0 8 2009 Check Number 845 Amount 500.00   |

431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

## APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE **CORPORATION**

FEE \$500.00 (non-refundable and not transferable) Application must be typed or printed legibly

| New Wholesaler  |  | ☐ Name Change       |        |
|---|--|---------------------|--------|
| FACILITY INFORMATION  |  |                     |        |
| Facility Name: <u>ACE</u> 501   | RGICAL SUPPLY                            | Co., Inc.           |        |
| Physical Address: 1034  |  |                     |        |
| Mailing Address:  |  |                     |        |
| City: BROCKton  | State:                                   | Zip Code: <i>_0</i> | 2301   |
| Telephone Number: 800-4   | <b>41-3100</b> Fax Numb                  | er: <u>800-58</u>   | 3-3150 |
| E-mail: info@ ace   | surgical com                             |                     |        |
| Facility Manager: <u>Craig</u>  |  |                     |        |
| Professional qualifications and enhance has been employed by is the generative of licensed outlets or authors.  |  |                     |        |
| ☐ Pharmacies ☑ Practition   |  |                     |        |
|   |  | ☐ Wholesalers       |        |
| ☐ Other <u>licensed phy</u> Type of Products to be handled  | sicians only                             |                     |        |
| □ Other <u>licensed phy</u>   | or wholesaled by firm  pplies or Devices |                     | evices |
| □ Other <u>licensed phy</u> Type of Products to be handled of Legend Pharmaceuticals, Supplementals of Controlled Substances (included)   | or wholesaled by firm  pplies or Devices | Hypodermic D        | evices |
| □ Other <u>licensed phy</u> Type of Products to be handled of Legend Pharmaceuticals, Su  □ Poisons or Chemicals □ Controlled Substances (included of the Legend Pharmaceuticals) | or wholesaled by firm  pplies or Devices |                     | evices |

431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

# APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be typed or printed legibly

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

| ***   |   |
|---|---|
| New Wholesaler  | Ownership Change   Name Change   (Please provide current license number if making changes: WH |
| FACILITY INFORMATION  |   |
| Facility Name: BRANT  | RANCH PREPACK   |
| Physical Address: 12623   | BANCH PREPACK SHERMAN WAY#A NORTHHOLYWOOD CA 9160S  |
| Mailing Address: 12623 S  | HERMAN WAY #A   |
| City: NORTH HOLLYWOOD   | State: Zip Code:91605   |
|   | -725 Fax Number: 877-277-7552   |
| E-mail: BRPPREPACK 6  | SBCGLOBAL, NET  |
| Facility Manager: OPIK  | DAWOODIAN   |
| Professional qualifications and example and planning technique                                  | perience of facility manager: Designated Representative                                       |
| Types of licensed outlets or autho  | rized persons firm will serve:  |
| ☐ Pharmacies ☐ Practitione☐ Other   | ers   Hospitals   Wholesalers   |
| Type of Products to be handled or   | wholesaled by firm  |
| Legend Pharmaceuticals, Supp<br>Poisons or Chemicals<br>Controlled Substances (include<br>Other | ,   |
| Board Use Only  |   |
| Received MAY 1 3 2009   | Check Number 984 Amount 500.00  |

50300 753

431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

# APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be typed or printed legibly

| New Wholesaler 💥   | Ownership Change   Name Change   (Please provide current license number if making changes: WH |
|--|---|
| FACILITY INFORMATION   |   |
| Facility Name: <u>Cardina</u>  | L NEClth  |
| Physical Address: <u>3840</u> £  | Im Point Industrial Dr  |
|  | as aboue  |
| City: ST Charles   | State: <u>mo</u> Zip Code: <u>63301</u>   |
| Telephone Number: 636-4  | <u> 43-8700</u> Fax Number: <u> </u>  |
| E-mail: <u>Lucus. Cacdine</u>  | wheelth.com   |
| Facility Manager: Rob Qu   | PRQENSEN  |
| Professional qualifications and  | experience of facility manager:   |
|  | me  |
|  |   |
| Types of licensed outlets or au  | thorized persons firm will serve:   |
| Pharmacies Practition  Other   |   |
| Type of Products to be handled   | d or wholesaled by firm   |
| Legend Pharmaceuticals, S  Poisons or Chemicals  Controlled Substances (incl Other | ☐ Veterinary Legend Drugs   |
| Board Use Only   |   |
| _  | G Check Number 376 Amount 500.00  |

# 555 Double Eagle Court #1100 • Reno, NV 89521 • (775) 850-1440

## APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable) Application must be typed or printed legibly

| New Wholesaler ⊠  | Ownership Change   Name Change   (Please provide current license number if making changes: WH |
|---|---|
| FACILITY INFORMATION  |   |
| Facility Name: DSC Logistics, Inc.  |   |
| Physical Address: 300 Gateway Parkw   | way, Roanoke TX 76262   |
| Mailing Address: 300 Gateway Parkwa   | зу  |
| City: Roanoke   | State: TX Zip Code: 76262   |
| Telephone Number: 817.961.7500  | Fax Number: 817.491.8240  |
| E-mail: CharlesHughes@dsc-logisitcs.com   | 1   |
| Facility Manager: Charles Evans Hughe   | es, Jr.   |
| Professional qualifications and evo   | perience of facility manager: Charles Evans Hughes, Jr. has several                           |
| years of experience with the pharmaceutical of  | 15  |
|   | distribution business.  |
| years of experience with the pharmaceutical of  | distribution business.  rized persons firm will serve:  |
| years of experience with the pharmaceutical of the pharmaceutical | rized persons firm will serve:  TS ☑ Hospitals ☐ Wholesalers                                  |
| years of experience with the pharmaceutical of the pharmaceutical | rized persons firm will serve:  rs  Hospitals   |

## 431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

# APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be typed or printed legibly

| New Wholesaler ⊠   | Ownership Change   Name Change   (Please provide current license number if making changes: WH   |
|--|---|
| FACILITY INFORMATION   |   |
| Facility Name: Sanvita, Inc.   |   |
| Physical Address: 615 South Ware   | Boulevard, Suite B, Tampa, Florida 33619  |
| Mailing Address: 14255 49th Stree  | et North, Suite 301   |
| City: Clearwater   | State: Florida Zip Code: 33762  |
| Telephone Number: 800-681-7571   | Fax Number: 727-507-2755  |
| E-mail: ccsmed.licensing@ccsmed.c  | com   |
| Facility Manager: Rusty Wright   |   |
| Representative. He is certified as   | Derience of facility manager:  Rusty is a Certified Designated s such in FL and CA. In addition, Rusty's employment history  Distribution for a retail/mail order pharmacy. |
| ☑ Pharmacies ☑ Practitione ☑ Other DME Suppliers   | rs   Hospitals   Wholesalers  |
| Type of Products to be handled or  | wholesaled by firm  |
| <ul> <li>☑ Legend Pharmaceuticals, Supp</li> <li>☑ Poisons or Chemicals</li> <li>☑ Controlled Substances (include</li> <li>☑ Other OTC Medical Devices (Glu</li> </ul> | lies or Devices  ☐ Hypodermic Devices ☐ Veterinary Legend Drugs copy of DEA certificate)  |
| Board Use Only   |   |
| Received MAY 13 2009   | Check Number 3052 Amount 500.60   |

431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

# APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be typed or printed legibly

|   | <u> </u>              |  |
|---|-----------------------|--|
| New Wholesaler  |                       | ☐ Name Change ☐ nse number if making changes: WH |
| FACILITY INFORMATION  |                       |  |
| Facility Name: Septodon 1   | , Inc.                |  |
| Physical Address: 345-C Qu  | igley Blud            |  |
| Mailing Address: P.O. Box   | 11926 K               | );/m. DE. 19850-1920                             |
| city: Now Castle  | State: DE             | Zip Code: 19720                                  |
| Telephone Number: 800-872-83  | ರ್_ Fax Numb          | er: <u>302-328-575</u> 3                         |
| E-mail: CSmith@so   | ptodontno             | , com  |
| Facility Manager: ANTHONY   | MONTEMU.              | RRO  |
|   |                       |  |
| Professional qualifications and experient   2 YEARS RESPO   | NSIBILITY FO          | OR DELAWARE                                      |
| FACILITY  | ,                     |  |
| Types of licensed outlets or authorized p   | nersons firm will ser | No.  |
|   |                       |  |
| ☐ Pharmacies ☐ Practitioners ☐ Other  | ☐ Hospitals           | Wholesalers                                      |
| Type of Products to be handled or whole   | esaled by firm        |  |
| Legend Pharmaceuticals, Supplies o Poisons or Chemicals Controlled Substances (include copy Other | r Devices             | ☐ Hypodermic Devices ☐ Veterinary Legend Drugs   |
| Board Use Only APR 16 2009 Received Chec  | k Number696           | Amount <i>500,<sup>co</sup></i>                  |

431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

## APPLICATION FOR NEVADA MDEG PROVIDER -PUBLICLY TRADED CORPORATION

FEE: \$500.00 (non-refundable and not transferable) - Application must be printed legibly

| New MDEG Provider X Ownership Change Name Change Please provide current license number if making change: MP  FACILITY INFORMATION  Facility Name: AIR GAS, NORTHERN CAURONNIA & NEUROA  Physical Address: 623 - FAIRSAOUNDS R.J. WINNEMUCCA, NV. 89445  (This must be a business address, we can not issue a license to a home address) |
|---|
| Facility Name: AIRGAS, NORTHERN CALLEORNIA & NEUROA   |
|   |
| Physical Address: 623 - FAIRSAOUNDS Rd. WINDEMUCCA, NV. 89445   |
| (This must be a business address, we can not issue a license to a home address)   |
| Mailing Address: 623- FAINSHOUNDS Rd.   |
| City: WINDEMUCEA State: NV. Zip Code: 89445   |
| Telephone Number: 775-625-2300 Fax Number: 775-625-2307   |
| DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING  |
| Mon: 8 to 5 Tue: 8 to 5 Wed: 8 to 5 Thu: 8 to 5   |
| Fri: $8 \text{ to } 5$ Sat: $- \text{ to } -$ Sun: $- \text{ to } -$ Holidays: $- \text{ to } -$  |
| FACILITY ADMINISTRATOR INFORMATION  |
| Name: Kenny Davis   |
| Address: 6 7025 - MOZANT CT.  |
| City: SUN Valley State: NV. Zip Code: 89433   |
| TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)  |
| X Medical Gases Assistive Equipment   |
| <u>X</u> Medical Gases Assistive Equipment Parenteral and Enteral Equipment   |
| Life-sustaining equipment Orthotics and Prosethics Other:   |
| If providing life-sustaining equipment, provide a 24-hour contact number: ()  |
| Board Use Only  |
| Received APR 0 8 2009 Check Number 263 Amount 500.00  |

431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440

# APPLICATION FOR NEVADA PHARMACY LICENSE NON PUBLICLY TRADED CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

| Pharmacy Name:   |   |                     |
|--|---|---------------------|
| Pharmacy Name:   | New Pharmacy Ownership Change Name Change (Please provide current license number if r | Location Change     |
| Physical Address:  | GENERAL INFORMATION   |                     |
| Physical Address:  | Pharmacy Name: <u>Center for Sungicul In</u>  | Hervertin, Lil      |
| City: Las Vegs State: N/ Zip: 89/13  Telephone Number: 702 562 30 39 Fax Number: 702 562 692 3  Toll Free Number: E-mail: MMOYA @ dk/empts.com  Managing Pharmacist: Maky Great RPh License Number: 1065 7  Hours of Operation:  Monday thru Friday 8 am 6 pm Saturday N/ am pm  Sunday N/4 am pm 24 Hours N/A  TYPE OF PHARMACY SERVICES PROVIDED  Retail Off-site Cognitive Services Hospital (# beds Parenteral (outpatient)  ASC Nuclear Parenteral (outpatient)  ASC Nuclear Mail Service Internet Long Term Care | Physical Address: 5950 S. Durango Da  |                     |
| City: Las Vegs State: N/ Zip: 89/13  Telephone Number: 702 562 30 39 Fax Number: 702 562 692 3  Toll Free Number: E-mail: MMOYA @ dk/empts.com  Managing Pharmacist: Maky Great RPh License Number: 1065 7  Hours of Operation:  Monday thru Friday 8 am 6 pm Saturday N/ am pm  Sunday N/4 am pm 24 Hours N/A  TYPE OF PHARMACY SERVICES PROVIDED  Retail Off-site Cognitive Services Hospital (# beds Parenteral (outpatient)  ASC Nuclear Parenteral (outpatient)  ASC Nuclear Mail Service Internet Long Term Care | Mailing Address: 9811 W Charleston Blvd #2-389 L                                      | V, Nv 89117         |
| Telephone Number: 702 562 30 39 Fax Number: 702 562 692 5  Toll Free Number: E-mail: May 6 de l'emper. Com  Managing Pharmacist: May 6 and 7 Ph License Number: 1068 7  Hours of Operation:  Monday thru Friday 8 am 6 pm Saturday May am pm  Sunday A am pm 24 Hours A A TYPE OF PHARMACY SERVICES PROVIDED    Retail   | City: LAS VegAS State: N/   | Zip: 89//3          |
| Managing Pharmacist: Maly Great RPh License Number: 10687  Hours of Operation:  Monday thru Friday 8 am 6 pm Saturday Mal am pm  Sunday 4 am pm 24 Hours Mal  TYPE OF PHARMACY SERVICES PROVIDED  Retail Off-site Cognitive Services Hospital (# beds _) Parenteral Correctional (# inmates _) Parenteral (outpatient)  ACC Nuclear Dutpatient/Discharge Out of State Mail Service Internet Long Term Care   |   |                     |
| Managing Pharmacist: Mary Great RPh License Number: 10637  Hours of Operation:  Monday thru Friday 8 am 6 pm Saturday M am pm  Sunday 4 am pm 24 Hours MA  TYPE OF PHARMACY SERVICES PROVIDED  Retail Off-site Cognitive Services Hospital (# beds _) Parenteral Correctional (# inmates _) Parenteral (outpatient)  ACC Nuclear Duty Outpatient/Discharge Out of State Mail Service Internet Long Term Care   | Toll Free Number: E-mail:   | MOYA @ dk/emper. co |
| Monday thru Friday 8 am 6 pm Saturday A am pm  Sunday A am pm 24 Hours A  TYPE OF PHARMACY  SERVICES PROVIDED  Retail Off-site Cognitive Services Parenteral Outpatient Parenteral (outpatient)  HOSC Nuclear Outpatient/Discharge Out of State Mail Service Internet Long Term Care   |   |                     |
| Sunday A am pm 24 Hours A SERVICES PROVIDED    Retail   Off-site Cognitive Services   Parenteral   Parenteral   Parenteral (outpatient)   Parenteral (outpatient)   Outpatient/Discharge   Out of State   Mail Service   Internet   Long Term Care   | Hours of Operation:   |                     |
| TYPE OF PHARMACY    Retail   | Monday thru Friday 8 am 6 pm Saturday 1   | <u>v /</u> am pm    |
| Retail Off-site Cognitive Services  Hospital (# beds) Parenteral  Correctional (# inmates) Parenteral (outpatient)  Correctional (# inmates) Outpatient/Discharge  Out of State Mail Service  Internet Long Term Care  | Sunday Ala_ ampm 24 Hours _   | NA                  |
| □ Hospital (# beds) □ Parenteral □ Correctional (# inmates) □ Parenteral (outpatient) □ Nuclear □ Mail Service □ Internet □ Long Term Care   | TYPE OF PHARMACY SERVICES PROVIDE   | <u>ED</u>           |
| ☐ Correctional (# inmates) ☐ Parenteral (outpatient) ☐ Nuclear ☐ Out of State ☐ Mail Service ☐ Internet ☐ Long Term Care  Board Use Only   | ☐ Retail ☐ Off-site Cognitive Se  | ervices             |
| A SC   | ☐ Hospital (# beds) ☐ Parenteral  |                     |
| Out of State   | ☑ □ Correctional (# inmates) □ Parenteral (outpatien                                  | nt)                 |
| ☐ Internet ☐ Long Term Care  Board Use Only  | ASC 🗆 Nuclear 🗷 Outpatient/Discharge  | e                   |
| Board Use Only   | ☐ Out of State ☐ Mail Service   |                     |
|  | ☐ Internet ☐ Long Term Care   |                     |
|  |   |                     |
| Received MAY 13 2009 Check Number 124 Amount 500.00  | · · · · · · · · · · · · · · · · · · ·   | C00 00              |
|  | Received MAY 13 2009 Check Number 124   | Amount 500,00       |

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

# APPLICATION FOR NEVADA PHARMACY LICENSE PARTNERSHIP

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

|                     |   |   | <u>-</u>     |
|---------------------|---|---|--------------|
| New Pharmacy        | Ownership Change Nam (Please provide current licens | ne Change Location Change<br>se number if making changes: PH)                     |              |
| GENERAL INFORMA     | ATION   |   |              |
| Pharmacy Name:      | solutions II - LI                                   | C   | <del>_</del> |
| Physical Address:   | 301 N PECOS RI                                      | 0AD SHITE B HENDERSTN.  | NV 891       |
| Mailing Address: 3  | OIN PECOS ROA                                       | HO SUITE B  |              |
| City: HENDER        | SON State:  | NV Zip Code: 89074  |              |
| Telephone Number:   | 702-792-3777 Fax                                    | C 0AD SUITE B HENDERSTN, HD SUITE B  NV Zip Code: 99074  Number: 702 - 792 - 1171 |              |
| Toll Free Number:   |   |   |              |
|                     | 157 @ SSPRX. COM Web                                | osite:  |              |
| Managing Pharmacist | : MATTHEW LASAR                                     | osite:<br>SO License Number:  3570  | ŧ            |
| Hours of Operation: |   | 0   |              |
| Monday thru Friday  | ):30 am (6:10 pm                                    | Saturday Clark am   | pm           |
| Sunday &            | 16.30 am (6:10 pm pm pm                             | 24 Hours  |              |
| •                   | F PHARMACY  | SERVICES PROVIDED   |              |
| ` <b>⊠</b> Retail   |   | ☐ Off-site Cognitive Services   |              |
| ☐ Hospi             | ital (# beds)                                       | ☐ Parenteral  | 1            |
| ☐ Intern            | et  | ☐ Parenteral (outpatient)   |              |
| ☐ Nucle             | ar  | ☐ Outpatient/Discharge  |              |
| ☐ Out of            | f State   | ☐ Mail Service  |              |
| ☐ Ambul             | atory Surgery Center                                | `⊠Long Term Care  |              |
| Board Use Only      |   |   |              |
| •                   | 2009check Number:                                   | Amount:   |              |

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

# APPLICATION FOR NEVADA PHARMACY LICENSE PUBLICLY TRADED CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

| New Pharmacy Ownership Change        | Name Change Location Change<br>t license number if making changes: PH) |
|--------------------------------------|--|
| (Flease provide curren               | r license number ir making changes. Ph                                 |
| GENERAL INFORMATION                  |  |
| Pharmacy Name: TARGET STORE T        | 2569   |
| Physical Address: 6371 N. DECATUR    | BLUP., LASUEGAS, NV 89130  |
| Mailing Address: 1000 NICOLLET MALL, | Troato   |
| City: MINNEAPOLIS State              | e: Zip Code:   |
| Telephone Number: 612-761-4912       |  |
| Toll Free Number:                    | _  |
| E-mail: Pharmey Licensing @ Target.  | Website:   |
| Managing Pharmacist: Andrew Roth     |  |
| Hours of Operation:                  |  |
| Monday thru Friday 10 am 8 pm        | Saturday <u>lø</u> am <u>6</u> pm                                      |
| Sunday <u>Il</u> am <u>5</u> pm      | 24 Hours No  |
| TYPE OF PHARMACY                     | SERVICES PROVIDED  |
| [2 Retail                            | ☐ Off-site Cognitive Services  |
| ☐ Hospital (# beds)                  | ☐ Parenteral   |
| ☐ Internet                           | ☐ Parenteral (outpatient)  |
| □ Nuclear                            | ☐ Outpatient/Discharge   |
| ☐ Out of State                       | ☐ Mail Service   |
| ☐ Ambulatory Surgery Center          | □ Long Term Care   |
| Board Use Only                       |  |
|                                      | 1701   |
| Received: MAY 13 2009 Check Number:  | 1796 Amount:   |

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

# APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

| application or subsequent revocation of the license issued and is    | a violation of the laws of the State of Nevada.        |
|--|--|
| New Pharmacy Ownership Change Name (Please provide current license n | Change Location Change<br>umber if making changes: PH) |
| GENERAL INFORMATION  |  |
| Pharmacy Name: College Pharmacy                                      |  |
| Physical Address: 3505 Austin Bluffs Pkwi                            | 1, Ste 101   |
| Mailing Address: <u>Same</u>   | ,  |
| City: Colorado Springs State: 10                                     | Zip Code: <u>809/8</u>                                 |
| Telephone Number: 7/9-262-0022 Fax Nu                                |  |
| Toll Free Number: 800-888-9358                                       |  |
| E-mail: info@collegephacmacy.com Website                             | =: www.collegenharmacu.com                             |
| Managing Pharmacist: Lecry Gillick                                   |  |
| Hours of Operation:  | CO 16960   |
| Monday thru Friday <u>8:30</u> am <u><i>6:0</i>0</u> pm              | Saturday <u>9:00</u> am <u>/0:00</u> pm                |
| Sunday <u>N/A</u> ampm   | 24 Hours   |
|  | SERVICES PROVIDED                                      |
| □ Retail □   | ☐ Off-site Cognitive Services                          |
| ☐ Hospital (# beds)  | ] Parenteral   |
| ☐ Internet ☐   | Parenteral (outpatient)                                |
| □ Nuclear □  | Outpatient/Discharge                                   |
| ☑ Out of State   | Mail Service   |
| ☐ Ambulatory Surgery Center ☐  | Long Term Care   |
| Board Use Only   |  |
| Received: APR 2 3 2009 Check Number: 491                             | Amount: 500,00   |

## **OWNERSHIP IS A CORPORATION**

| State of Incorporation: <u>Colorado</u>  |
|--|
| Parent Company if any:   |
| Corporation Name: College Pharmacy, Inc.   |
| Mailing Address: 3505 Austin Bluffs Pkuly, Ste 101   |
| City: Colorado Springs State: CO Zip: 80918  |
| Telephone: 719 - 262 - 0022 x 178 Fax: 719 - 955 - 1490  |
| License Contact Person: SANDY ESTREDGE   |
| Professional Compliance Contact Person: JERRY GILLICK, RPh - PARMARY MAYAGE  |
| Ownership Information – Complete Section 1 or 2 <u>Do not use N/A in this section – Section 1 or 2 must be completed.</u>  |
| Section 1: List the corporations four largest shareholders: (Name and percentage of ownership)   |
| 1. College Pharmacy, Inc. Employee Stock Ownership %: 100  |
| 2  |
| 3  |
|  |
| 4 %:   |
| Section 2: If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.  Date of Incorporation:  Registration number issued:  Stock Exchange: |
| List any physician shareholders and percentage of ownership:  NA   |
| If corporation is a subsidiary, list name and state of incorporation of the parent corporation and include a list officers. $N/\beta$  |

| Withir | the last five (5) years:  |               |       |            |
|--------|---|---------------|-------|------------|
| 1)     | Has the firm or any owner(s), shareholder(s) with at least 10% interest, offi or director(s) thereof, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?                      | cer(s)<br>Yes | No.   | 9          |
| 2)     | Has the firm or any owner(s), shareholder(s) with at least 10% interest, officer or director(s) thereof, ever been denied a license, permit or certificate of registration?   |               | ⊠ No  |            |
| 3)     | Has the firm or any owner(s), shareholder(s) with at least 10% interest, office or director(s) thereof, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry?                                    | cer(s)<br>Yes | No No |            |
| 4)     | Has the firm or any owner(s), shareholder(s) with at least 10% interest, office or director(s) thereof, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | , ,           | □ No  | <b>\( </b> |
|        | Has the firm or any owner(s), shareholder(s) with at least 10% interest, office or director(s) thereof, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | . ,           | te No | $\Box$     |

If the answer to any question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Signature of owner or executive officer

PHARMACY OPERATIONS

Print or Type name and title

GILLICK, VIGE PRESIDEM,



April 17, 2009

Nevada State Board of Pharmacy 431 West Plumb Lane Reno, Nevada 89509

Re: Explanation to Application Questions

In response to the questions on page 3 of the Application for Out-Of-State Pharmacy License, I have the following explanations:

- 1. In December 2007, the United States District Court for the District of Colorado initiated an indictment against College Pharmacy and the previous owner of College Pharmacy, Tom Bader, for purchasing and distributing Human Growth Hormone without proper new drug application and approval. In January 2008, Tom Bader sold College Pharmacy to the College Pharmacy, Incorporated Employee Stock Ownership Trust so he is no longer involved with College Pharmacy. In September 2008, College Pharmacy entered into a Settlement Agreement with the United States of America, removing College Pharmacy from the indictment.
- 2. College Pharmacy has been denied a non-resident pharmacy license in Florida, Indiana, Nevada, and North Carolina. We are reapplying to Nevada and North Carolina now that the legal issues have been resolved. We are currently in negotiations with Florida and Indiana for licensure.
- 3. College Pharmacy was issued a Stipulation Order by the Colorado Board of Pharmacy in December 2005 for record-keeping and labeling errors. The terms of that order has been completed. The Colorado Board of Pharmacy issued a Summary Suspension against College Pharmacy and Tom Bader in October 2007. The Summary Suspension has been dismissed. The Colorado Board of Pharmacy issued a Stipulation Order in December 2007 as a result of the federal indictment. This Stipulation Order has been amended as of April 10, 2009 as a result of the complaint regarding the purchase of a commercial product from a supplier that is not registered with Colorado. In March 2009, Jerry Gillick, a director on the Board for the College Pharmacy, Inc. ESOP, was issued a Letter of Admonition for purchasing a commercial drug from a company that was not registered in Colorado.

- 4. There have been no federal or state offenses related to a controlled substance which have resulted in a guilty verdict, guilty plea or plea of nolo contendere in regards to the pharmacy, any owner(s), shareholder(s) with at least 10% interest, officer(s), or director(s) within the last five years.
- 5. In October 2007, the previous owner, Tom Bader, surrendered his Colorado Pharmacist license to the Board of Pharmacy, as a result of the Summary Suspension issued by the Colorado Board of Pharmacy.

I have already provided an explanation of the Letter of Admonition against me as I am currently licensed in Nevada. However, if you need further explanation of any part of the above, please call me at 719-262-0022 ext. 123.

Sincerely,

Jerry Gillick, R.Ph. Pharmacist-in Charge College Pharmacy 719-262-0022 ext.123

# CORPORATE STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

| 1, JERRY GILLICK  |  |  |  |  |
|---|--|--|--|--|
| Corporate Officer of COLLEGE PHARMACY INC.  |  |  |  |  |
| hereby acknowledge and understand that in addition to the corporation's                 |  |  |  |  |
| responsibilities, my fellow officers and I, as corporate officers of said corporation,  |  |  |  |  |
| may be responsible for any violations of pharmacy law that may occur in a pharmacy      |  |  |  |  |
| owned or operated by said corporation.  |  |  |  |  |
| I further acknowledge and understand that the corporate officers may be                 |  |  |  |  |
| named in any action taken by the Nevada State Board of Pharmacy against a               |  |  |  |  |
| pharmacy owned by or operated by said corporation.                                      |  |  |  |  |
| I further acknowledge and understand that the corporation cannot require or             |  |  |  |  |
| permit the pharmacist(s) in said pharmacy to violate any provision of any local, state  |  |  |  |  |
| or federal laws or regulations pertaining to the practice of pharmacy or operation of a |  |  |  |  |
| pharmacy in Nevada.   |  |  |  |  |
| I further acknowledge and understand that upon the change of managing                   |  |  |  |  |
| pharmacist in the pharmacy, the corporation must assure that an accountability audit    |  |  |  |  |
| of all controlled substances shall be performed jointly by the departing managing       |  |  |  |  |

April 14,2009 Date

pharmacist and the new managing pharmacist.

# STATE OF COLORADO

# DIVISION OF REGISTRATIONS OFFICE OF SUPPORT SERVICES

Joann Crouse, Office Director

1560 Broadway, Suite 1350 Denver, Colorado 80202-5146 Phone (303) 894-7800 Fax (303) 894-7693 TTY: Dial 711 for Relay Colorado www.dora.state.co.us/registrations

College Pharmacy 3505 AUSTIN BLUFFS PKY COLORADO SPRINGS CO 80918 **Department of Regulatory Agencies** 

D. Rico Munn

**Executive Director** 

Division of Registrations Rosemary McCool Director



Bill Ritter Jr. Governor

April 2, 2009

#### LICENSE VERIFICATION

### College Pharmacy

Profession: Prescription Drug Outlet- In-State

License number: 240000038 Licensee Status: Active

Original Date of Issue: 01/01/1988

Basis of: Original

Last renewed on 10/06/2008 Expiration date: 10/31/2010

Authority Type: Authority Number: Authority Start Date: Authority End Date: Authority Cancel Date:

Board or Program action(s): Y

N = No Y = Yes

If there is board or program action(s) against this licensee and you need additional information, please send a written request to the Board at the address above or email <a href="mailto:pharmacy@dora.state.co.us">pharmacy@dora.state.co.us</a>. Or, you can view Registrations Online Documents (ROD) at www.dora.state.co.us/doraimages. This online system makes certain scanned documents related to actions taken on all Colorado licensees available to the public via the Internet. Stipulations, Final Agency Orders, and Suspensions that were in effect in February 2000, plus any that became effective since that date, are among the documents that are now available.

For future reference, you may verify the current status at any time through ALISON, the Automated Licensure System Online, at http://www.dora.state.co.us/registrations

FOR THE COLORADO BOARD OF PHARMACY

Marge Bennett Marge A. Bennett-OSS

**Customer Support Representative** 

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO

Civil Action No. 08-cv-01790-MSK-CBS

UNITED STATES OF AMERICA,

Plaintiff,

v.

COLLEGE PHARMACY, INCORPORATED,

Forfeiture and Injunctive Defendant,

and

COLLEGE PHARMACY, INCORPORATED EMPLOYEE STOCK OWNERSHIP TRUST RACHEL CHRISTOPHER, TRUSTEE,

Injunctive Defendant.

### CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, having filed this action by filing its Complaint for Permanent Injunction, and College Pharmacy, Incorporated ("College Pharmacy") and College Pharmacy, Incorporated Employee Stock Ownership Trust ("College Pharmacy ESOP"), having appeared and consented to the entry of this Decree of Permanent Injunction without contest and before any testimony was taken, and the United States of America, having consented to this Decree of Permanent Injunction;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

- 1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over the parties to this action.
- 2. The parties agree that the Complaint for Permanent Injunction states a cause of action against College Pharmacy, Incorporated under the Federal Food, Drug, and Cosmetic Act (the

"Act"), 21 U.S.C. § 301, et seq. The Complaint alleges that between 2003 and 2007, when Thomas Bader was its owner, College Pharmacy violated 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce human growth hormone within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(I).

3. College Pharmacy and College Pharmacy ESOP, who presently owns College Pharmacy, have appeared in this action and consented to entry of this Decree of Permanent Injunction, for the purpose of resolving this case and Criminal Action No. 07-cr-00338-MSK. The government agrees to dismiss without prejudice the criminal charges against College Pharmacy brought in Case No. 07-cr-00338-MSK, said dismissal being contingent upon College Pharmacy's encouragement and facilitation of ongoing cooperation of its employees and officers with the government's prosecution of the case, College Pharmacy's entry into this Settlement Agreement for Forfeiture and Entry of Consent Decree of Permanent Injunction, and Entry of the Consent Decree of Permanent Injunction by the Court; the parties agree that should College Pharmacy and College Pharmacy ESOP fail to comply with the terms of the Settlement Agreement for Forfeiture and the Consent Decree, the United States may re-institute the criminal charges. The government also consents to the entry of this Decree of Permanent Injunction because the time frame of the alleged violations of law contained in the indictments and in the complaint filed in this action covers a period of time from January, 2003 through June, 2007. During that time frame, Thomas Bader, was the owner of College Pharmacy. Presently, Thomas Bader no longer owns and operates College Pharmacy, nor does he have any involvement with College Pharmacy ESOP. On December 18, 2007, Defendant Bader entered into an agreement,

entitled "Stipulation and Final Agency Order", with the Colorado State Board of Pharmacy ("State Board"). Pursuant to that agreement, Mr. Bader permanently relinquished his pharmacy license, transferred all of his stock in College Pharmacy to College Pharmacy ESOP, resigned as both director and sole officer, and agreed not to participate in the management or operation of College Pharmacy in the future. The transfer/sale was completed on January 15, 2008 and College Pharmacy ESOP is now the record owner of College Pharmacy and controls its management and operation.

- 4. College Pharmacy and College Pharmacy ESOP represent that: (i) neither Thomas W. Bader, nor any member of his family, by blood or by marriage, is employed by College Pharmacy in any capacity, including as a consultant, nor involved, in any manner, in any of College Pharmacy's pharmacy operations;1 and (ii) College Pharmacy shall never employ either Thomas W. Bader, nor any member of his family, by blood or by marriage, in any capacity, including as a consultant; and (iii) College Pharmacy shall never permit either Thomas W. Bader, nor any member of his family, by blood or by marriage, to become involved, in any manner, in any of College Pharmacy's pharmacy operations.
- 5. Upon entry of this Decree of Permanent Injunction, College Pharmacy and College Pharmacy ESOP agree to the following:
  - a. It will file all hGH (including somatropin) and Schedule III (including

<sup>&</sup>lt;sup>1</sup>The parties recognize, however, that College Pharmacy 1 presently leases its place of business from an entity in which Thomas Bader has an interest. In addition, Mr. Bader's Stipulation and Final Agency Order, with the Colorado State Board of Pharmacy, specifically permits Thomas Bader to have access to a small office in the same building and requires College Pharmacy to allow Mr. Bader "access to his records and those of College Pharmacy so that he may aid in his defense of the criminal charges now pending against him." Finally, College Pharmacy notes that it has some minor business interrelationships with Thomas Bader, which College Pharmacy will be terminating within 60 days.

testosterone), Schedule IV, and Schedule V prescriptions separate from allother prescriptions and other records. Otherwise, it will comply with the Controlled Substances Act, 21 U.S.C. §§ 827, 829, and 841 et seq., and all applicable regulations in the Code of Federal Regulations, Title 21, Parts 1304 and 1306; b. It will refrain from introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce hGH (including somatropin) other than hGH (including somatropin) that is (i) contained in an FDA approved drug product, (ii) dispensed pursuant to a patient-specific prescription, and (iii) for approved uses only, as determined by the Secretary of Health and Human Services or the FDA; and

- c. Notwithstanding this paragraph, nothing herein prohibits CollegePharmacy and each and all of its directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree of Permanent Injunction by personal service or otherwise from engaging in the practice of pharmacy, including compounding of drugs, pursuant to state or federal laws. Notwithstanding, College Pharmacy understands that DEA will conduct a pre-registration investigation on its pending application to be registered with DEA as a practitioner pharmacy and take appropriate action on the application.
- 6. Within five (5) calendar days of FDA's, DEA's, or any of their designees' request for prescription records for any somatropin and testosterone (including testosterone cypionate) dispensed by College Pharmacy, College Pharmacy agrees to submit a copy of the requested

materials to the FDA, DEA, or any of their designees, in the manner directed by FDA, DEA, or any of their designees.

- 7. Within five (5) calendar days of FDA's, DEA's, or any of their designees' request for any records related to College Pharmacy's sale, distribution, dispensing, procurement or other actions introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce somatropin, College Pharmacy shall submit a copy of the requested materials to the FDA, DEA, or any of their designees, in the manner directed by FDA, DEA, or any of their designees.
- 8. Within thirty (30) calendar days of entry of this Decree of Permanent Injunction, College Pharmacy shall retain an independent person or persons (the "expert"), without personal, financial (other than the consulting agreement between the parties), or familial ties to College Pharmacy or any officer or director of College Pharmacy or their immediate families, who by reason of background, experience, education, and training is qualified to assess College Pharmacy's compliance with the Controlled Substances Act. At the conclusion of the expert's review, the expert shall confer and work with College Pharmacy's directors and officers to confirm that College Pharmacy is acting in compliance with federal and state law.
- 9. Duly authorized representatives of FDA, DEA, or any of their designees shall be permitted, without prior notice and as and when FDA, DEA, or any of their designees deems necessary, to make inspections of College Pharmacy's facilities and records, including, but not limited to, business records, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree of Permanent Injunction. During such inspections, FDA, DEA, or designee representatives shall be permitted prompt access to buildings, equipment, in-process and finished materials, containers, labeling

and other materials therein; to take samples of College Pharmacy's finished and unfinished materials and products, containers, labels, labeling, and other promotional materials; and to examine and copy all records relating to the receipt, compounding, packing, labeling, promoting, holding and distribution of any and all College Pharmacy's products in order to ensure continuing compliance with the terms of this Decree of Permanent Injunction.<sup>2</sup> The inspections shall be permitted upon presentation of a copy of this Decree of Permanent Injunction and appropriate credentials. The inspection authority granted by this Decree of Permanent Injunction is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374, but is limited to the inspection rights specified in paragraphs 6, 7, and 9 of this Consent Decree of Permanent Injunction.

10. Within ten (10) calendar days after the entry of this Decree of Permanent Injunction, College Pharmacy shall provide a copy of this Decree of Permanent Injunction, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of its directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including "doing business as" entities) (hereafter collectively referred to as "associated persons"). Within thirty-five (35) calendar days of the date of entry of this Decree of Permanent Injunction, College Pharmacy shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all associated persons who have received a copy of this Decree of Permanent Injunction and the manner of notification. In the event that College Pharmacy becomes associated, at any time after the entry of this Decree

<sup>&</sup>lt;sup>2</sup>The government inspectors agree that they will inform College Pharmacy of any and all records it copies during any inspection.

of Permanent Injunction, with new associated persons, College Pharmacy shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Decree of Permanent Injunction to each such associated person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree of Permanent Injunction was provided.

- 11. Within ten (10) calendar days of entry of this Decree of Permanent Injunction,

  College Pharmacy shall post a copy of this Decree of Permanent Injunction on a bulletin board
  in a common area at all of College Pharmacy's compounding or dispensing facilities, and shall
  ensure that the Decree of Permanent Injunction remains posted for a period of twelve (12)
  months at each location.
- 12. College Pharmacy shall pay a forfeiture judgment, entered by the Court in a separate order, to the United States in the total amount of \$3,500,000, as follows:
  - a. No later than beginning on March 1, 2009, College Pharmacy shall make monthly payments to the United States by the fifteenth (15th) calendar day of each month. The settlement sum shall be remitted in the form of certified funds, made payable to the United States Marshals Service, and submitted to the U.S. Attorney's Office per instructions provided by the United States;
  - b. The payment amount for a particular month shall, at a minimum, be the lesser of the following: (I) \$95,565; (ii) the College Pharmacy's "Net Profits" (as that term is defined below) for the Calculation month (as defined below); or (iii) the difference between three million five hundred thousand dollars (\$3,500,000) and the total sum of payments made by the College Pharmacy as of that date.

For purposes of this settlement, (a) "Net Profits" shall mean the gross revenue of

College Pharmacy, less all outlays and expenses, including, but not limited to, operating expenses, payments on all types of debt and other liability, excluding all payments due to Thomas Bader pursuant to the promissory note executed between College Pharmacy and Thomas Bader, but including pension plans, taxes, principal and interest payments; and (b) Calculation Month shall mean the month immediately preceding the month ending prior to the date the monthly settlement is due. To ensure that College Pharmacy is paying the lesser of \$95,565 or Net Profits for the Calculation Month, College Pharmacy will provide the United States with a verified financial statement within six weeks from the date of payment for the previous month that shows an accounting of College Pharmacy's Net Profits for that month as defined above;

- c. College Pharmacy may decide, in its sole discretion and in any month, to make a payment greater than the amount described in Paragraph 12(b) above;
- d. College Pharmacy shall make payments totaling at least \$850,000.00 within the first year, or by March 1, 2010; payments totaling \$2,000,000.00 within the first two years, or by March 1, 2011; and payments totaling the full forfeiture judgment of \$3,500,000.00 within three years, or by March 1, 2012;
- e. College Pharmacy shall continue to make monthly payments until the total sum of the payments made by College Pharmacy to the United States reaches \$3,500,000.00; and
- f. In the event College Pharmacy is unable to meet the payment schedule described above, College Pharmacy may seek an extension of time for payment from the United States if College Pharmacy has been making good faith payments

and seeks an extension of time prior to the date that the payment is due. The parties understand that such an extension remains within the exclusive discretion of the United States.

- 13. College Pharmacy's obligation to fulfill the \$3,500,000.00 forfeiture judgment is non-dischargeable in the event College Pharmacy files for bankruptcy because the forfeiture judgment is based on intentional conduct by College Pharmacy, by and through its officers and employees.
- 14. Three (3) years after the date of entry of this Decree of Permanent Injunction, or when College Pharmacy pays the agreed money judgment of \$3,500,000.00, which shall be forfeited to the United States, whichever is later, if neither the FDA, DEA, nor any of their designees has notified College Pharmacy that there has been a significant violation of this Decree of Permanent Injunction or the Act during such time, College Pharmacy may petition the Court to dissolve this Decree of Permanent Injunction. The determination of the significance of a violation will be solely within the discretion of the FDA, DEA, or any of their designees.
- 15. This Decree of Permanent Injunction shall be enforceable in contract and under the contempt powers of the Court.
- 16. Upon demand by the United States for non-compliance by College Pharmacy of the payment terms of this Decree of Permanent Injunction outlined in paragraph 12, the United States is entitled to the immediate turnover of all assets, including, but not limited to, funds, bank accounts, real and personal property, accounts receivable, stocks, and investments belonging to College Pharmacy, Incorporated. In the event of non-compliance, this Decree shall be construed as a turnover order for all assets, including, but not limited to, funds, bank accounts, real and personal property, accounts receivable, stocks, and investments belonging to

College Pharmacy, Incorporated, whether held by College Pharmacy, Incorporated or College Pharmacy, Incorporated Employee Stock Ownership Trust, without further petition of the Court by the United States.

17. College Pharmacy and College Pharmacy, Incorporated Employee Stock
Ownership Trust shall not transfer ownership of assets, stocks, or receivables without prior
approval from the United States, which will not be unreasonably withheld.

18. This Consent Decree of Permanent Injunction shall bind the agents, principles, affiliates, successors, assigns, personal representatives, and heirs of the United States, College Pharmacy, Incorporated, and College Pharmacy, Incorporated Employee Stock Ownership Trust.

19. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree of Permanent Injunction and for the purpose of granting such additional relief as may be necessary or appropriate.

Dated this 26th day of January, 2009

BY THE COURT:

Marcia S. Krieger

United States District Judge

marcie S. Kniga

## STATE OF COLORADO

#### STATE BOARD OF PHARMACY

Wendy L. Anderson, Program Director

1560 Broadway, Suite 1300 Denver, Colorado 80202-5146 Phone (303) 894-7800 Fax (303) 894-7692 TTY: Dial 711 for Relay Colorado www.dora.state.co.us/pharmacy

## **Department of Regulatory Agencies**

D. Rico Munn **Executive Director** 

**Division of Registrations** Rosemary McCool Director

Bill Ritter, Jr. Governor

February 1, 2008

College Pharmacy Attn: Sandy Estredge, Administration 3505 Austin Bluffs Parkway, Suite 101 Colorado Springs, CO 80918

College Pharmacy, PDO RE:

Case #2004-0055 and Case #2005-4152

Dear Ms. Estredge:

The Stipulation and Final Agency Order you requested on the above licensee or registrant is attached. This Stipulation and Final Agency Order became effective on the date signed.

The licensee successfully completed the terms of this Stipulation and Final Agency Order.

The licensee has not yet completed the terms of the Stipulation and Final Agency Order as of this date. The licensee is considered to be in compliance with the document's terms until such time as any subsequent action would become final.

If you wish information in addition to what is contained in the Final Agency Order, you may request an appointment to review the licensee file or you may place specific questions in writing to the Board for its response.

THE BOARD OF PHARMACY

Complaint Analyst

### BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2005-0002

### STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE REGISTRATION FOR COLLEGE PHARMACY, REGISTRATION NO. 24-38

### Respondent.

.............

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy, ("the Board") and College Pharmacy, ("Respondent") as follows:

- 1. The Board has jurisdiction over the person of Respondent and the subject matter of this Stipulation and Final Agency Order ("Stipulation and Order").
- 2. Respondent has been registered as a prescription drug outlet in the State of Colorado at all times relevant to this disciplinary action.
- 3. This Stipulation and Order is a full and final resolution of case number 2005-0002, and Board complaints 2004-055, 2005-4152 and 2005-4151. This Stipulation and Order does not resolve any other cases, complaints or matters, as of the effective date of this Stipulation and Order.
  - 4. Respondent admits and the Board finds:
    - a. Pharmacists employed by Respondent failed to engage in proper due diligence and dispensed prescriptions to a practitioner's office under employee names, rather than under a specific patient's name;
    - b. From June 10, 2003 through June 11, 2003, pharmacists employed by Respondent compounded and dispensed three prescription orders to Dr. Gioia as office use medication, each order was for five 10ml vials of testosterone cypionate 200 mg/ml. Respondent labeled the prescriptions for office use;
    - c. Due to a record-keeping error the above prescription orders for Dr. Gioia did not list the patient's address; and
    - d. Due to a record-keeping error, Respondent did not have specific compounding records for an order for four 10 ml vials of estradiol cypionate 5 mg/ml prepared on October 11, 2002, nor could Respondent tell who conducted the final evaluation for this order on said date.

- 5. By virtue of the facts in paragraph 4 above, the Board finds Respondent violated C.R.S. § § 12-22-125(1)(c), 12-22-121(1),12-22-123(2), 12-22-126(1)(m), 18-18-306, 21 C.F.R. § 1306.05, and Rules 2.01.10(a) and (e), 3.00.20, 3.00.50(a), and 14.00.10 (currently 11.01.00) as specified below in paragraph 6 below.
  - 6. The relevant statutory authority of the Board is as follows:

### 12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

\*\*\*

- (c) Has violated:
- (I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;
- (II) The lawful rules of the board; or
- (III) Any state or federal law pertaining to drugs.

\*\*\*

# 12-22-121 Compounding, dispensing, and sale of drugs and devices.

(1) Except as otherwise provided in this section and part 3 of this article, no drug, controlled substance, as defined in section 12-22-303(7), or device shall be sold, compounded, dispensed, given, received, or held in possession unless it is sold, compounded, dispensed, given, or received in accordance with this section.

#### 12-22-123. Labeling.

\*\*\*

(2) Except as otherwise required by law, any drug dispensed pursuant to a prescription order shall bear a label prepared and placed on or securely attached to the medicine container stating at least the name and address of the prescription drug outlet, the serial number, and the date of the prescription or of its filling, the name of the drug dispensed unless otherwise requested by the practitioner, the name of the practitioner, the name of the patient, and, if stated in the prescription, the directions for use and cautionary statements, if any, contained in such prescription.

### 12-22-126 Unlawful acts. (1) It is unlawful:

\*\*\*

(m) To dispense any drug without complying with the labeling, drug identification, and container requirements imposed by law.

\*\*\*

- 18-18-306. Records of registrants. Persons registered to manufacture, distribute, or dispense controlled substances under this part 3 shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with any additional rules adopted by the board or department.
- 21 C.F.R. § 1306.05 Manner of issuance of prescriptions. (a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. . . . A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by these regulations.

#### Rules of Professional Conduct.

- 2.01.10 Information to appear on each order. The following information must appear on each written or oral order except as provided except as provided for chart orders:
- a. The name, initials, or license number of the pharmacist making the final evaluation as required by regulation; and

\*\*\*

- e. In the case of a controlled substance order, the patient address, prescriber address, and prescriber's DEA registration.
- 3.00.20 Medical need. No licensee or registrant shall compound, dispense, deliver or distribute any drug to any person in such quantity or in any situation where the licensee or registrant knows or reasonably should know said drug has no recognized medical utility or application. Violation of this rule shall constitute prima facie proof of violation of CRS 12-22-125.

The pharmacist may not dispense a prescription drug or a controlled substance to a practitioner based on an order that does not list a specific patient. A prescription order for "office use" is not a valid order.

3.00.50 Final evaluation. Each time a prescription drug or device is dispensed in a prescription drug outlet, a pharmacist shall make

the final evaluation of the transaction. At the time of such final evaluation, the pharmacist shall take whatever action is necessary to ensure that the initial interpretation, container, label, and prescription drug or device dispensed, as well as all records relating to the transaction are complete, accurate, and appropriate.

(a). The record or records of each dispensing transaction shall bear the identity of the pharmacist making the final evaluation, and this pharmacist shall be held responsible and accountable for each dispensing transaction which bears this pharmacist's identity.

14.00.10 Records in general. All outlets registered and/or licensed by the Board shall maintain such records and inventories of prescription drugs as may be required by these regulations or any other state or federal law or regulation pertaining to such drugs. Such records shall be maintained on a current basis and shall be complete and accurate for all drugs which the outlet manufactures, receives, dispenses, distributes or otherwise disposes of in any other manner. Records and inventories of controlled substances shall be maintained in compliance with CRS 12-22-300 et seq., 18-18-100 et seq., these regulations, and all applicable sections of 21 Code of Federal Regulations 1300 to End, which is hereby incorporated by reference.

All such records may be microfilmed or retained by any process providing an exact duplicate of the original order in a reproducible quality acceptable to the Board. These records may be stored using alternate recordkeeping systems including but not limited to electronic, magnetic, light, laser, or optic media. Any such storage media must meet industry standards for quality and have stability for a period of at least two years after the date of any transaction relating to such record or inventory.

Records on an automated data processing system or subsequent storage of such records must be immediately retrievable (via CRT display or hard copy printout). Upon Board approval, outlets capable of meeting the above standards may not be required to retain the original prescription order.

### DISPOSITION

7. <u>FINE:</u> Respondent shall hereby pay a fine of \$50,000, payable to the State of Colorado.

- 8. <u>OUARTERLY REPORTS</u>: For a period of four years from the effective date of this Stipulation, Respondent agrees to submit to the Board quarterly reports on casual sales in a provable manner as follows:
  - a. Reports are to detail the total number of dosage units dispensed to patients in the quarter;
  - b. Reports are to detail how many dosage units are distributed to a Practitioner or other Pharmacy in the quarter;
  - c. Reports must contain an affidavit affirming that no prescriptions for drugs were dispensed in violation of 12-21-121(6)(b), C.R.S.; and
  - d. Reports for the previous quarter will be due on the 15<sup>th</sup> of January, April, July and October.

### 9. OTHER TERMS:

- a. Throughout the term of this Stipulation and Order, Respondent shall attend any meeting with the Board upon 30 days notice if the Respondent resides in Colorado and 60 days notice if the Respondent resides out of state;
- b. Respondent shall comply fully with this Stipulation and Order; and
- c. Respondent shall comply fully with the Colorado Pharmacy Laws, all Board rules and regulations, and any other State and Federal laws related to pharmacies and the practice of pharmacy.

#### **ADVISEMENTS AND WAIVERS**

- 10. <u>ADVISEMENT AND WAIVERS.</u> Respondent is aware of and understands his right to receive a formal notice of hearing and charges and to have a formal disciplinary hearing pursuant to § 12-22-125.2(2)(a), C.R.S. (2005) and hereby waives those rights and requests that this Stipulation and Order be accepted by the Board with the same force and effect as an order entered into as a result of a formal disciplinary proceeding. Respondent further waives the right to appeal the Order entered herein.
- 11. This Stipulation and Order is entered into by Respondent voluntarily, after the opportunity to consult with counsel and with full understanding of the legal consequences of this Stipulation and Order.
- 12. Respondent acknowledges and agrees that any violation of this Stipulation and Order shall constitute a violation of a lawful Board Order and grounds for further proceedings pursuant to the Pharmaceuticals and Pharmacists Law and, if proven, may constitute a basis for further disciplinary action. In the event this matter is referred to hearing for violation of this Stipulation and Order, this Stipulation and Order shall be admissible as evidence. In the event an

alleged violation of this Stipulation and Order is taken to hearing and the facts that constitute the violation are determined to be not proven, no disciplinary action shall be taken by the Board and this Stipulation and Order shall remain operative and in full force and effect. The pendency of any disciplinary action pursuant to this Stipulation and Order shall not affect the obligation of Respondent to comply with the terms of this Stipulation and Order.

- 13. <u>INTEGRATION AND SEVERABILITY</u>. This Stipulation and Order constitutes the entire agreement between Respondent and the Board. There are no other promises expressed or implied. In the event that a provision is deemed unenforceable by a court of competent jurisdiction, such provision shall be severed, and the remainder of this Stipulation and Order shall be given full force and effect.
- Respondent has adhered to all terms and conditions of this Stipulation and Order, Respondent's Stipulation shall be deemed completed and Respondent may request termination of the Stipulation. Request for termination of the Stipulation must be made in writing to the Board, and Respondent is solely responsible for establishing, through written and other documentation satisfactory to the Board, that he has satisfied all terms and conditions of this Stipulation.
- 15. <u>OTHER CONDITIONS.</u> In the event this Stipulation and Order does not become an Order of the Board, it shall be void and Respondent shall not be bound by any provisions hereof or admissions herein.
- 16. <u>PUBLIC RECORD.</u> This Stipulation and Order is a public record in the custody of the Board at all times and shall be reported as required by law.
- 17. <u>EFFECTIVE DATE</u>. This Stipulation and Order shall become an Order of the Board when accepted by the Board and signed by an authorized Board member or agent for the Board.

[Signature pages follow.]

### AGREED TO AND ACCEPTED BY:

| RESPONDENT                   | COLORADO STATE BOARD OF PHARMACY |  |  |
|------------------------------|----------------------------------|--|--|
|                              |                                  |  |  |
|                              | the Pyland                       |  |  |
| College Pharmacy             | By: (Thoan L. Warren             |  |  |
| NAME                         | SUSAN L. WARREN                  |  |  |
| Tollie                       | Program Director                 |  |  |
| By: Tom Bader, Its President | 1560 Broadway, #1310             |  |  |
| •                            | Denver, CO 80202                 |  |  |
|                              |                                  |  |  |
|                              | - st                             |  |  |
| Address                      | Effective Date: This 2 day       |  |  |
|                              | - of December, 2005.             |  |  |
| Telephone Number             | of <i>petter vell</i> , 2005.    |  |  |

### APPROVED AS TO FORM:

FREDERICK BALL, ESQ.

Duane Morris LLP 227 West Monroe Street Chicago, IL 60606 (312) 499-6722 JOHN W. SUTHERS

JOYCE R/COHEN, 35209\* Assistant Attorney General Business and Licensing Section

Attorneys for the Colorado State Board of Pharmacy

1525 Sherman St., 5<sup>th</sup> Floor Denver, CO 80203 303) 866-5453 \*Counsel of Record



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| STATE OF COLORADO   | C40007                |
|---|-----------------------|
| STATE OF COLORADO OFFICE OF ADMINISTRATIVE COURTS               | ADMINISTRATIVE COURTS |
| 633 17 <sup>th</sup> Street, Suite 1300, Denver, Colorado 80202 |                       |
| COLORADO STATE BOARD OF PHARMACY,                               |                       |
| Petitioner,   |                       |
| vs.   | ▲ COURT USE ONLY ▲    |
| <b>70.</b>  | Case No.: PH 2007-    |
| COLLEGE PHARMACY,   |                       |
| REGISTRATION No. PDO #240000038,                                |                       |
| and   |                       |
| THOMAS W. BADER, R.PH.,   |                       |
| LICENSE No. 9321,   |                       |
| Respondents.  |                       |
| ORDER OF SUMMARY SUSPENSION. NOTICE OF                          | DUTY TO ANSWED NOTICE |

ORDER OF SUMMARY SUSPENSION, NOTICE OF DUTY TO ANSWER, NOTICE TO SET AN INFORMAL PREHEARING CONFERENCE, NOTICE OF HEARING, AND NOTICE OF CHARGES

#### TO: COLLEGE PHARMACY

#### ORDER OF SUMMARY SUSPENSION

The State Board of Pharmacy ("Board"), having conducted an investigation as to the matters referenced below, HEREBY FINDS:

- 1. College Pharmacy ("Respondent Pharmacy") has been located in the State of Colorado at all times relevant herein.
- 2. The Board has jurisdiction over Respondent Pharmacy and the subject matter herein.
- 3. Based on the information referenced in the attached Notice of Charges, reasonable grounds exist to believe, and the Board so finds, that Respondent Pharmacy has deliberately and

willfully violated the Pharmaceuticals and Pharmacists Act, Board Rules, and sections of the United States Code.

4. Based on the information referenced in the attached Notice of Charges, reasonable grounds exist to believe, and the Board so finds, that the public health, safety, and welfare imperatively require that emergency action be taken.

THEREFORE, IT IS HEREBY ORDERED that the registration of College Pharmacy as a prescription drug outlet in the State of Colorado be, and hereby is, summarily suspended pursuant to §24-4-104(4)(a), C.R.S. pending proceedings to determine whether Respondent Pharmacy's registration as a prescription drug outlet in the State of Colorado should be further disciplined in accordance with §812-22-125 and 12-22-125.2, C.R.S.

Pending the outcome of said proceedings, IT IS FURTHER ORDERED that College Pharmacy:

- a. immediately cease, desist, and refrain from any further acts for which a registration as a prescription drug outlet is required by the laws of the State of Colorado upon receipt of this Summary Suspension; AND
- b. within ninety six (96) hours of receipt of this Summary Suspension, submit its registration card to the Board; AND
- c. within ninety six (96) hours of receipt of this Summary Suspension, prepare a complete, detailed inventory of all drugs in Respondent Pharmacy, including the name, strength, and quantity of each drug; AND
- d. within ninety six (96) hours of receipt of this Summary Suspension, provide a written copy of said complete, detailed inventory to the Board; AND
- e. within ninety six (96) hours of receipt of this Summary Suspension, remove all drugs and records, including all files and dispensing records, to another registered location; AND
- f. within ninety six (96) hours of receipt of this Summary Suspension, notify the Board in writing of the name, address, registration number, and DEA registration number of the location to which said drugs and records have been removed.

TO: THOMAS W. BADER, R.PH.

### ORDER OF SUMMARY SUSPENSION

Based on its investigation conducted as to the matters referenced below, the Board HEREBY FURTHER FINDS:

- Thomas W. Bader, R.Ph. ("Respondent Bader") was issued Colorado pharmacy license no. 9321 on June 23, 1969, and has been licensed in the State of Colorado at all times relevant herein.
- 2. The Board has jurisdiction over Respondent Bader and the subject matter herein.
- 3. Based on the information referenced in the attached Notice of Charges, reasonable grounds exist to believe, and the Board so finds, that Respondent Bader has deliberately and willfully violated the Pharmaceuticals and Pharmacists Act, Board Rules, and sections of the United States Code pursuant to §24-4-104(4)(a), C.R.S.
- 4. Based on the information referenced in the attached Notice of Charges, reasonable grounds exist to believe, and the Board so finds, that the public health, safety, and welfare imperatively require that emergency action be taken pursuant to §24-4-104(4)(a), C.R.S.

THEREFORE, IT IS HEREBY FURTHER ORDERED that the license of Thomas W. Bader to practice pharmacy in the State of Colorado be, and hereby is, summarily suspended pursuant to §24-4-104(4)(a), C.R.S. pending proceedings to determine whether his license to practice pharmacy in the State of Colorado should be further disciplined in accordance with C.R.S. §§12-22-125 and 12-22-125.2, C.R.S.

Pending the outcome of said proceedings, IT IS FURTHER ORDERED that Thomas W. Bader immediately:

- a. cease, desist, and refrain from any further acts for which a license to practice pharmacy is required by the laws of the State of Colorado, and
- b. submit his license card to the Board pending the outcome of this proceeding.

DATED this 19 day of October, 2007.

Wendy Anderson

Program Director

Colorado State Board of Pharmacy

### **NOTICE OF DUTY TO ANSWER**

Land Control

RESPONDENTS COLLEGE PHARMACY AND THOMAS W. BADER, R.PH. (hereinafter "Respondents") ARE HEREBY NOTIFIED that, pursuant to §24-4-105(2)(b), C.R.S., Respondents are hereby required to file a written answer to the attached Notice of Charges with the Office of Administrative Courts, 633 Seventeenth Street, Suite 1300, Denver, CO 80202, within thirty (30) days after the service of this Order of Summary Suspension, Notice of Duty to Answer, Notice to Set an Informal Prehearing Conference, Notice of Hearing, and Notice of Charges. Respondents must also mail a copy of such answer to the Board's attorney who has signed this Notice of Duty to Answer, Notice to Set an Informal Prehearing Conference, Notice of Hearing, and Notice of Charges below.

If Respondent Pharmacy fails to file its written answer within thirty (30) days, an order entering a default decision may be issued against its Colorado registration as a prescription drug outlet for the relief requested in the Notice of Charges, without further notice, or such other penalties which may be provided for by law, without further notice.

If Respondent Bader fails to file his written answer within thirty (30) days, an order entering a default decision may be issued against his license to practice pharmacy in the state of Colorado for the relief requested in the Notice of Charges, without further notice, or such other penalties which may be provided for by law, without further notice.

### NOTICE TO SET AN INFORMAL PREHEARING CONFERENCE

RESPONDENTS ARE HEREBY NOTIFIED that the attorney for the State Board of Pharmacy, State of Colorado, will appear at 9:30 a.m. on November 9, 2007, in the Office of Administrative Courts, 633 Seventeenth Street, Denver, CO 80202 in order to set a date and obtain a location for a prehearing conference regarding the following Notice of Charges. At the informal prehearing conference, the parties will obtain a hearing date, arrange an expedited discovery schedule, and obtain motion dates as necessary. Respondents may be present in person by a representative, by counsel, or by telephone by calling the Office of Administrative Courts at (303) 866-2000 at the time and date indicated above.

#### NOTICE OF HEARING

RESPONDENTS ARE HEREBY NOTIFIED that pursuant to §§12-22-110, 12-22-125, 12-22-125.2, 24-4-104, and 24-4-105, C.R.S., a hearing will be held before an authorized administrative law judge at a time and location to be determined pursuant to the preceding prehearing conference for the purpose of determining whether the registration of Respondent Pharmacy and/or the license of Respondent Bader should be revoked or other lawful discipline imposed for a violation or violations of or pursuant to the relevant portions of the Pharmaceuticals and Pharmacists Act at §§12-22-101 et seq., Pharmacy Board Rules at 3 CCR 719-1 (eff. 7/31/04), and 21 U.S.C. §§301, et seq., which provide as follows:

### Colorado Revised Statutes

### 12-22-125. Unprofessional conduct - grounds for discipline.

- (1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:
- ...(c) Has violated:
  - (I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;
  - (II) The lawful rules of the board; or
  - (III) Any state or federal law pertaining to drugs.
- ...(h) Has engaged in advertising that is misleading, deceptive, or false;
- ...(k) Has failed to meet generally accepted standards of pharmacy practice;
- ...(m) Has violated any lawful board order;
- 12-22-125.2. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

### 12-22-120. Registration of facilities.

- (1) All outlets with facilities in this state shall register with the board in one of the following classifications:
  - (a) Prescription drug outlet;
  - (b) Wholesale drug outlet;
  - (c) Manufacturing drug outlet:
  - (d) Repealed.
  - (e) Any other outlet, as may be authorized by this article or that meets the definition of outlet as set forth in section 12-22-102(23).

#### 12-22-126. Unlawful acts.

- (1) It is unlawful:
- ...(c) To willfully make a false statement in any order, report, application, or record required by this part 1;

### 12-22-128. New drugs - when sales permissible.

(1) No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law.

#### 18-18-102. Definitions.

As used in this article:

- (3) (a) "Anabolic steroid" means any material, drug, hormonal compound, salt, isomer or salts of isomers of testosterone, or synthetic or natural derivatives of testosterone having pronounced anabolic properties which is used primarily to promote growth of muscle tissue, which includes, but is not limited to, any of the following:
- (XI) Human growth hormone...

#### 18-18-205. Schedule III.

- (2) Unless specifically excepted by Colorado or federal law, or Colorado or federal regulation, or more specifically included in another schedule, the following controlled substances are listed in schedule III:
- ...(e) Anabolic steroids.

#### 21. U.S.C. § 331. Prohibited acts

The following acts and the causing thereof are prohibited:

...(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 355, or 360bbb-3 of this title.

### 21 U.S.C. §333. Penalties

...(e) Prohibited distribution of human growth hormone

- (1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, or both.
- ...(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

### 21 U.S.C. § 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

### Pharmacy Rules and Regulations

- 1.00.11 A pharmacist shall at all times conduct his/her profession in conformity with all federal and state drug laws, rules and regulations; and shall uphold the legal standards of the current official compendia.
- 1.00.12 A pharmacist shall not be a party or accessory to nor engage in any fraudulent or deceitful practice or transaction in pharmacy, nor knowingly participate in any practice which detrimentally affects the patient, nor discredit his/her profession.
- 3.00.20 Medical Need. No licensee or registrant shall compound, dispense, deliver or distribute any drug to any person in such quantity or in any situation where the licensee or registrant knows or reasonably should know said drug has no recognized medical utility or application. Violation of this rule shall constitute prima facie proof of violation of CRS 12-22-125.

The pharmacist may not dispense a prescription drug or a controlled substance to a practitioner based on an order that does not list a specific patient. A prescription order for "office use" is not a valid order.

### 3.01.00 Prepackaging and repackaging

#### 3.01.10

- a. In a prescription drug outlet prepackaging and repackaging shall only be done by a pharmacist, or by an intern or an unlicensed assistant under the supervision of a pharmacist. In an other outlet, prepackaging and repackaging may be done by a person not licensed as a pharmacist pursuant to protocols approved by the Board.
- b. Such packaged drugs shall only be dispensed or distributed from the premises where prepackaged or repackaged. Such drugs shall only be distributed to a location which is under the same ownership as, or is contractually affiliated with, the premises where prepackaged or repackaged.
- 3.01.20 Each prepackaged container, whether for use in a unit dose distribution system or a traditional dispensing system, shall be labeled in accordance with this regulation. Any repackaged unit dose, single dose or unit of issue container for which return for restocking and redispensing, pursuant to 3.00.80, is anticipated, shall be labeled in accordance with this regulation. Additionally, any repackaged container from which subsequent dispensing may occur, shall be labeled in accordance with this regulation. Such labeling shall include at least the following:
- ...(b) A suitable expiration date, which shall be not later than the expiration date on the manufacturer's container, or one year from the date the drug is prepackaged or repackaged...

### 7.00.30 Compliance of Outlet:

a. The manager of a prescription drug outlet is responsible for the operation of the outlet in compliance with all state and federal laws, rules, and regulations.

\* \* \*

RESPONDENTS ARE FURTHER NOTIFIED that at the hearing in this matter Respondents shall have the right to appear by representative and/or by legal counsel; to present evidence in their own behalf; to cross-examine any witnesses presented by the State Board of Pharmacy; and to rebut any evidence presented by the State Board of Pharmacy. Respondents may also have subpoenas issued on their behalf upon request to the administrative law judge.

<sup>&</sup>lt;sup>1</sup> Effective March 31, 2007, Board Rule 3.01.20(b) was amended to add the phrase "whichever is less" at the end of the paragraph.

### **NOTICE OF CHARGES**

The State Board of Pharmacy charges and alleges as follows:

### General Allegations

- Respondent Pharmacy was registered as a prescription drug outlet in 1974, was issued PDO # 24000038, and has been registered as a prescription drug outlet and located in the State of Colorado at all relevant times.
- 2. Respondent Bader was issued Colorado pharmacy license no. 9321 on June 23, 1969, and has been licensed as a pharmacist in the State of Colorado at all relevant times.
- 3. The Board has jurisdiction over the Respondent Pharmacy, its registration as a prescription drug outlet, Respondent Bader, his license to practice pharmacy, and the subject matter of this proceeding and the Notice of Charges pursuant to the provisions of §§12-22-101, et seq., C.R.S.
- 4. Respondent Bader was the pharmacist manager at all relevant times.

### Specific Allegations

- 5. On December 21, 2005, Respondent Pharmacy entered into a Stipulation and Final Agency Order ("2005 Stipulation") in which Respondent Pharmacy was charged a fine of \$50,000 for violations of state law and Board rules, and was required to submit quarterly reports on casual sales for a period of four years. In paragraph 9(c) of the 2005 Stipulation, Respondent Pharmacy agreed to "comply fully with the Colorado Pharmacy Laws, all Board rules and regulations, and any other State and Federal laws related to pharmacies and the practice of pharmacy."
- 6. Respondent Bader signed the 2005 Stipulation on behalf of Respondent Pharmacy.
- 7. At all relevant times, the FDA has considered all human growth hormone ("hGH") products to be "new drugs" within the meaning of federal law.
- 8. At all relevant times, federal law has required an approval by the FDA of an application for any new drug to be in effect prior to its introduction or delivery for introduction into interstate commerce in the United States.
- 9. At all relevant times, only FDA-approved human growth hormone ("hGH"); i.e., hGH with an approval of an application by the FDA in effect, can legally be introduced or delivered for introduction into interstate commerce in the United States.

- 10. At no time has the FDA or the Secretary of Health and Human Services ever approved an application for somatropin produced in China or manufactured in any facility in China.
- 11. In or around September, 2004, Respondent Bader held meetings at Respondent Pharmacy involving several staff members, during which meetings the purchase of hGH in the form of "somatropin" lyophilized powder manufactured in and/or imported from China ("Chinese somatropin") was discussed.
- 12. In or around September of 2004, Respondent Pharmacy began purchasing Chinese somatropin from a supplier known as "Hawk Biopharma," for resale, dispensing and/or distribution. Respondent Pharmacy listed Hawk Biopharma as the manufacturer of the somatropin in its records.
- 13. Purchase of the Chinese somatropin from Hawk Biopharma for resale, dispensing and/or distribution was done under the direction of Respondent Bader.
- 14. Hawk Biopharma has two addresses: 1400 North Harbor Blvd., Suite 640, Fullerton, California, 92835, and 32 Wallich Street, #03-61 Wallich Building, Singapore, 078880.
- 15. No company by the name of Hawk Biopharma has ever had an FDA approved new drug application in effect for somatropin.
- 16. At a date uncertain but no later than September of 2006, Respondent Pharmacy began purchasing Chinese somatropin from a supplier known as "North America GeneScience," for resale, dispensing and/or distribution. Respondent Pharmacy listed "GeneScience" as the manufacturer of the somatropin in its records.
- 17. Purchase of the Chinese somatropin from North America GeneScience for resale, dispensing and/or distribution was done under the direction of Respondent Bader.
- 18. North America GeneScience LLC is located at 1270 Crabb River Road, Suite 600 28 in Richmond, Texas.
- 19. North America GeneScience has never had an FDA approved new drug application in effect for somatropin.
- 20. The somatropin provided to Respondent Pharmacy by North American GeneScience was manufactured by GeneScience Pharmaceuticals Co. LTD.
- 21. GeneScience Pharmaceuticals Co. LTD is located at: 1 Tianhe St., Changchun High Tech Dev Zone, 130012, Changchun Jilin, China.
- 22. GeneScience Pharmaceuticals Co. LTD has never had an FDA approved new drug application in effect for somatropin.

- 23. From the latter part of 2004 until approximately July of 2007, Respondent Pharmacy sold or otherwise transferred the Chinese somatropin described above in paragraphs 12 through 22 to doctors, individuals and other entities inside and outside the State of Colorado.
- 24. At all relevant times, FDA-approved hGH can only be legally prescribed in the United States for a limited number of conditions authorized by the Secretary of Health and Human Services, including:
  - Hormonal deficiency that causes short stature in children;
  - Long-term treatment of growth failure due to lack of exogenous GH secretion;
  - Long-term treatment of short stature associated with Turner syndrome;
  - Adult short bowel syndrome;
  - · Adult deficiency due to rare pituitary tumors or their treatment; and
  - Muscle-wasting disease associated with HIV/AIDS.
- 25. The conditions listed above in paragraph 24 are generally uncommon conditions.
- 26. The most common condition of those listed above in paragraph 24 is hormonal deficiency causing short stature in children.
- 27. At all relevant times, the distribution or possession with the intent to distribute hGH for antiaging, bodybuilding, athletic enhancement, or any other use not approved by the FDA was prohibited by federal law.
- 28. During the relevant times, Respondent Pharmacy distributed marketing documents designed to promote the sale of hGH for "treatment" of the "symptoms" of age, including but not limited to: reduction of body fat, increase of muscle mass, improvement of skin texture and libido, and increased strength and energy. The marketing documents noted that anti-aging clinics throughout the United States "came to" Respondent Pharmacy "for solutions to their age management questions." The marketing documents bore titles such as "Turn Back the Clock," "Adios Adipose!," and "Live Life to the Fullest."
- 29. During the relevant times, the majority of Chinese somatropin Respondent Pharmacy sold was ultimately intended for dispensing to adult consumers.
- 30. Within a seven-day period from approximately November 22 through 29, 2004 Respondent Pharmacy repackaged approximately 230 vials of somatropin acquired from Hawk Biopharma, for resale or other transfer.
- 31. Respondent Pharmacy provided an expiration date of "7/31/06" in the documentation of the vials repackaged during November 22 through 29, 2004.

- 32. On or around December 2, 2004, Respondents repackaged at least six vials of Chinese somatropin powder, assigned an expiration date of "2006 12" to each vial, and labeled each vial with the following: Country of Origin: China."
- 33. Within a five-day period from approximately September 15 through 19, 2006, Respondent Pharmacy repackaged approximately 500 vials of somatropin acquired from "GeneScience," for resale or other transfer.
- 34. Respondent Pharmacy provided an expiration date of "2/28/2008" in the documentation of the vials repackaged during September 15 through 19, 2006.
- 35. At times between September of 2005 and July of 2007, the Chinese somatropin described above in paragraphs 12 through 22 was one of the top-selling drugs at Respondent Pharmacy.
- 36. At all relevant times, Respondent Pharmacy's method of processing the Chinese somatropin was to transfer lyophilized hGH powder from large vials into smaller vials in smaller portions for sale or other transfer under Respondent Pharmacy's name.
- 37. When Respondent Pharmacy began selling Chinese somatropin in 2004, Respondent Bader instructed staff members to refer to the method of handling the Chinese somatropin as "repackaged hGH."
- 38. Under Colorado law, repackaging drug products by a pharmacy constitutes manufacturing and requires registration as a manufacturer in the State of Colorado unless they are to be distributed to a location which is under the same ownership as, or is contractually affiliated with, the premises where prepackaged or repackaged.
- 39. Respondent Pharmacy distributed the Chinese somatropin it repackaged to locations not under the same ownership as, or contractually affiliated with, the premises where Respondent Pharmacy repackaged the Chinese somatropin.
- 40. Repackaging by Respondent Pharmacy and distribution to locations not under the same ownership as, or contractually affiliated with, the premises where Respondent Pharmacy repackaged the Chinese somatropin, required it to be registered as a manufacturing outlet in the State of Colorado.
- 41. Respondent Pharmacy was not registered as a manufacturing outlet in the State of Colorado during the relevant times.
- 42. As pharmacist manager, Respondent Bader was responsible for the operation of Respondent Pharmacy in compliance with all state and federal laws, rules, and regulations at all times.
- 43. Respondent Bader, either personally or through his agents, represented to various staff members and/or employees of Respondent Pharmacy that their processing, sale and/or

distribution of Chinese somatropin did not violate any laws and that they were doing nothing wrong.

#### Grounds for Discipline

#### Count I

- 44. Paragraphs 1 through 43 are incorporated herein by reference.
- 45. Beginning in September of 2004, and continuing through approximately July of 2007, Respondents College Pharmacy and Thomas W. Bader, R.Ph. purchased Chinese somatropin that was not an FDA-approved drug, and introduced such drug into interstate commerce.
- 46. Purchasing a non FDA-approved drug, and introducing such drug into interstate commerce, violates 21 U.S.C. §§331 and 355, and §12-22-128(1), C.R.S.
- 47. Respondents violated 21 U.S.C. §§331 and 355, and §12-22-128(1), C.R.S.
- 48. The violations described in paragraph 47 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(III) and 12-22-125(1)(k), C.R.S.

#### Count II

- 49. Paragraphs 1 through 48 are incorporated herein by reference.
- 50. Respondents College Pharmacy and Thomas W. Bader, R.Ph. circulated advertisements for somatropin as "treatment" for the "symptoms" of aging, including but not limited to: reduction of body fat, increase of muscle mass, improvement of skin texture and libido, and increased strength and energy, and noting that anti-aging clinics throughout the United States "came to" Respondent Pharmacy " for solutions to their age management questions," including the availability of hGH.
- 51. HGH can only legally be prescribed and administered for a limited number of FDA-approved conditions, none of which includes anti-aging or the effects of aging, body-building, athletic enhancement, or any other use not approved by the FDA.
- 52. Circulation of advertisements such as those described above in paragraph 50 violates §12-22-125(1)(h), C.R.S.
- 53. Respondents violated §12-22-125(1)(h), C.R.S.
- 54. The violations described in paragraph 53 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) and 12-22-125(1)(k), C.R.S.

#### Count III

- 55. Paragraphs 1 through 54 are incorporated herein by reference.
- 56. Respondents College Pharmacy and Thomas W. Bader knowingly distributed, and/or possessed with intent to distribute, hGH for uses in humans other than the treatment of diseases or other recognized medical conditions other than those recognized by the Secretary of Health and Human Services as approved pursuant to 21 U.S.C. §355.
- 57. Knowing distribution, or possession with intent to distribute, hGH for any use in humans other than the treatment of a disease or other recognized medical condition authorized by the Secretary of Health and Human Services as evidenced by approval pursuant to 21 U.S.C. §355 violates 21 U.S.C. §333(e).
- 58. Respondents violated 21 U.S.C. §333(e).
- 59. The violations described in paragraph 58 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) and 12-22-125(1)(k), C.R.S.

#### Count IV

- 60. Paragraphs 1 through 59 are incorporated herein by reference.
- 61. There is no recognized medical utility or application of somatropin or other forms of hGH for anti-aging or the effects of aging, body-building or athletic enhancement.
- 62. Respondents College Pharmacy and Thomas W. Bader sold, distributed and/or dispensed Chinese somatropin to persons in quantities and situations where Respondent Pharmacy knew or reasonably should have known the Chinese somatropin had no recognized medical utility or application.
- 63. Selling, distributing and/or dispensing any drug to any persons in such quantity or in any situation where the registrant knew or reasonably should have known the drug has no recognized medical utility or application violates Board Rule 3.00.20.
- 64. Respondents violated Board Rule 3.00.20.
- 65. The violations described in paragraph 64 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(II) and 12-22-125(1)(k), C.R.S.

#### Count V

66. Paragraphs 1 through 65 are incorporated herein by reference.

- 67. Respondents College Pharmacy and Thomas W. Bader repackaged the Chinese somatropin and/or caused it to be repackaged by taking the Chinese somatropin from large vials in which it was provided by the supplier and placing it into smaller vials containing smaller amounts.
- 68. Respondents repackaged and distributed Chinese somatropin to a location or locations not under the same ownership as Respondent Pharmacy nor contractually affiliated with Respondent Pharmacy's premises where the Chinese somatropin was repackaged.
- 69. Repackaging for distribution to a location or locations not under the same ownership as a prescription drug outlet where the repackaging occurs, nor contractually affiliated with the premises where the prepackaging occurs, is prohibited pursuant to Board Rule 3.01.10.
- 70. Repackaging for distribution to a location or locations not under the same ownership as a prescription drug outlet where the repackaging occurs, or is contractually affiliated with the pharmacy's premises, constitutes "manufacturing" pursuant to Board Rule 3.01.10.
- 71. Respondent Pharmacy was not registered as a manufacturing outlet at any relevant time.
- 72. Manufacturing a drug in the State of Colorado without a manufacturer's registration violates §12-22-120, C.R.S.
- 73. Respondents violated §12-22-120, C.R.S. and Board Rule 3.01.10.
- 74. The violations described in paragraph 73 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) and (II) and 12-22-125(1)(k), C.R.S.

#### Count VI

- 75. Paragraphs 1 through 74 are incorporated herein by reference.
- 76. Respondents College Pharmacy and Thomas W. Bader placed, and/or caused to be placed, expiration dates beyond one year from the date the Chinese somatropin was repackaged on repackaged vials of Chinese Somatropin.
- 77. Placing expiration dates beyond one year from the date a drug was repackaged violates §12-22-126, C.R.S. and Board Rule 3.01.20.
- 78. Respondents violated §12-22-126, C.R.S. and Board Rule 3.01.20.
- 79. The violations described in paragraph 78 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) and (II), and 12-22-125(1)(k), C.R.S.

### Count VII

- 80. Paragraphs 1 through 79 are incorporated herein by reference.
- 81. By engaging in the above-described violations of provisions of part 1 of the Pharmaceuticals and Pharmacists Act, the lawful rules of the Board, and other state and federal laws pertaining to drugs, Respondent Pharmacy violated the terms of its 2005 Stipulation.
- 82. Violations of the 2005 Stipulation constitute violations of a lawful Board order in violation of §12-22-125(1)(m), C.R.S.
- 83. Respondent violated §12-22-125(1)(m), C.R.S.
- 84. The violations described in paragraph 83 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(II) and 12-22-125(1)(k), C.R.S.

#### Count VIII

- 85. Paragraphs 1 through 84 are incorporated herein by reference.
- 86. Respondent Bader, as pharmacist manager, was responsible for the operation of Respondent Pharmacy in compliance with all state and federal laws, rules, and regulations.
- 87. Respondent Bader failed to operate Respondent Pharmacy in compliance with all state and federal laws, rules and regulations in each instance of each violation set forth above in paragraphs 44 through 84.
- 88. Failure, as pharmacist manager, to be responsible for the operation of the outlet in compliance with all state and federal laws, rules and regulations violates Board Rule 7.00.30(a).
- 89. The violations described above in paragraph 88 provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) through (III) and 12-22-125(1)(k), C.R.S.

#### Count IX

- 90. Paragraphs 1 through 89 are incorporated herein by reference.
- 91. By violating any statute or Board Rule, or committing any of unlawful acts set forth above in Counts I through VIII, a pharmacist violates Board Rule 1.00.11.
- 92. Respondent Bader violated Board Rule 1.00.11 in the instance of each of the violations set forth above in Counts I through VIII, and is subject to discipline under §§12-22-125(1)(c)(I) through (III) and 12-22-125(1)(k), C.R.S.

#### Count X

- 93. Paragraphs 1 through 92 are incorporated herein by reference.
- 94. By being a party or accessory to, or engaging in a fraudulent or deceitful practice or transaction in pharmacy, or knowingly participating in any practice which detrimentally affects the patient, or discredits the profession, a pharmacist violates Board Rule 1.00.12.
- 95. Respondent Bader violated Board Rule 1.00.12, and is subject to discipline under §§12-22-125(1)(c)(I) through (III) and 12-22-125(1)(k), C.R.S.

WHEREFORE, the Board prays for an Order revoking, suspending, or otherwise appropriately disciplining College Pharmacy's Colorado registration as a prescription drug outlet, and Thomas W. Bader's license to practice as a pharmacist in the state of Colorado, and for such other relief as deemed proper and just.

DATED this Change of October 2007.

JOHN SUTHERS Attorney General

JOANNA LEE KAYE, #20486\* JACK WESOKY, #6001\*

Assistant Attorneys General Business and Licensing Section

Attorneys for State Board of Pharmacy

1525 Sherman Street, 5th Floor Denver, Colorado 80203 Telephone: (303) 866-6170

FAX: (303) 866-5395 \*Counsel of Record

# **CERTIFICATE OF MAILING**

This is to certify that I have duly served the within ORDER OF SUMMARY SUSPENSION, NOTICE OF DUTY TO ANSWER, NOTICE TO SET AN INFORMAL PREHEARING CONFERENCE, NOTICE OF HEARING, AND NOTICE OF CHARGES upon all parties herein via facsimile transmission and by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 4 day of 2007, addressed as follows:

Charles H. Torres, Esq. 1700 Broadway, Suite 2120 Denver, Colorado 80290

Howard M. Hoffmann, Esq. 227 West Monroe Street, Suite 3400 Chicago, Illinois 60606

and via interoffice mail:

Wendy Anderson
Program Director
Colorado State Board of Pharmacy

| STATE OF COLORADO  |                |
|--|----------------|
| OFFICE OF ADMINISTRATIVE COURTS                                |                |
| 633 17 <sup>th</sup> Street, Suite 1300 Denver, Colorado 80202 |                |
|  |                |
| COLORADO STATE BOARD OF PHARMACY,                              |                |
| Petitioner,  | COURT USE ONLY |
| vs.  |                |
|  | CASE NUMBER:   |
| COLLEGE PHARMACY, PDO #240000038                               | PH 2007-0012   |
| and  |                |
| THOMAS W. BADER, R.Ph., License No. 9321, Respondents.         |                |
| ORDER OF DISMISSAL   |                |

The undersigned Administrative Law Judge, having reviewed the Board's Motion to Dismiss with respect to the above-captioned proceeding and being fully advised in its premises, hereby does:

### ORDER

The above-captioned proceeding is dismissed.

**DONE AND SIGNED** this 29 day of January, 2008.

ROBERT N. SPENCER Administrative Law Judge

### CERTIFICATE OF SERVICE

I hereby certify that I have mailed a true and correct copy of the above **ORDER OF DISMISSAL** by placing same in the U.S. Mail, postage prepaid, at Denver, Colorado to:

Charles H. Torres, Esq. 1700 Broadway, Suite 2120 Denver, CO 80290

Howard M. Hoffmann, Esq. 227 West Monroe Street, Suite 3400 Chicago, II 60606

and served same by courier pickup on: Joanna Lee Kaye, Assistant Attorney General, Business and Licensing Section, 1525 Sherman Street, 5th Floor, Denver, CO 80203, on this 30 day of January, 2008.

Office of Administrative Courts

# BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

OAC Case No. PH 2007-0003 (Board Case No. 2008-569)

# STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE AND REGISTRATION OF COLLEGE PHARMACY, PDO# 240000038, IN THE STATE OF COLORADO AS A PRESCRIPTION DRUG OUTLET,

Respondent.

11 ....

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and College Pharmacy, Inc., d/b/a College Pharmacy ("Respondent" or "College Pharmacy") to resolve all matters pertaining to College Pharmacy in Case No. PH2007-0003 (Board Case Number 2008-569), as follows:

# FINDINGS AND CONCLUSIONS

- The Board has jurisdiction over Respondent, its registration as a prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmacists and Pharmaceuticals Act at Title 12, Article 22, C.R.S.
- Respondent was originally registered as a prescription drug outlet in the State of Colorado in 1974, and has been so registered at all times relevant to this disciplinary action.
- Respondent's address of record with the Board is College Pharmacy, 3505 Austin Bluffs Parkway, Ste. 101, Colorado Springs, Colorado 80918.
- 4. On or about October 19, 2007, the Board entered an order, pursuant to §24-4-104(4)(a) C.R.S., summarily suspending Respondent's registration as a prescription drug outlet in the state of Colorado pending proceedings to determine whether its registration should be further disciplined in accordance with §§ 12-22-125 and 125.2, C.R.S., and the Board filed with the Office of Administrative Courts, and Respondent was served with, a Notice to Set, Notice of Hearing, Notice of Duty to Answer, and Notice of Charges (hereafter "NOC," attached to this Final Agency Order) for violations of §§12-22-101 et seq., ("Pharmaceuticals and Pharmacist Act") and Pharmacy Board Rules at 3 CCR 719-1 (3/31/06) ("Board Rules") based on the factual allegations set forth in the NOC, under Office of Administrative Courts Case No. PH 2007-0003.

- Respondent denies the allegations in the NOC, denies committing the violations alleged in the NOC and by entering into this Final Agency Order makes no admissions of any facts alleged in the NOC or that any conduct alleged violated any state or federal law.
- 6. Thomas Bader is the owner of all outstanding shares of College Pharmacy, Inc., ("CPI") and is transferring said shares to an Employee Stock Ownership Plan ("ESOP") which ESOP will become the record owner of all shares of stock of CPI with current employees of Respondent being the beneficial owners. Based in part on this transfer, the parties agree to resolve the NOC and the disposition of this matter as set forth below.

### DISPOSITION

7. Transfer of Ownership. The transfer of the shares of stock described in paragraph 6 above shall be finalized and the sale of such stock closed on or before January 15, 2008. If such closing does not occur this Stipulation and Final Agency Order shall be null and void and the Board may summarily suspend Respondent's registration and set the NOC for hearing. Respondent shall not contest the Summary Suspension by any means either by action in district court or in this matter before the Office of Administrative Courts. Nothing herein however shall be construed to prohibit Respondent from contesting the NOC.

# 8. Obligations after transfer.

- (a) No later than 4:00 P.M. on January 15, 2008, Respondent shall submit its completed Transfer of Ownership application to the Board's offices. With such application Respondent shall submit documentation demonstrating that formation of the ESOP and that the transfer of the stock of CPI into the ESOP has been completed. If Respondent fails to meet these obligations, at the sole option of the Board, this Stipulation shall be null and void and the Board may summarily suspend Respondent's registration and set the NOC for hearing. Respondent shall not contest the summary suspension by any means either by action in district court or in this matter before the Office of Administrative Courts. Nothing herein however shall be construed to prohibit Respondent from contesting the NOC.
- (b) On or before 4:00 P.M. on January 15, 2008, Respondent shall submit all controlled substance dispensing transactions from July 1, 2007 through December 31, 2007, to Colorado's Electronic Prescription Drug Monitoring program in the required format. If Respondent fails to do so, at the sole option of the Board, this Stipulation shall be null and void and the Board may summarily suspend Respondent's registration and set the NOC for hearing. Respondent shall not contest the summary suspension by any means either by action in district court or in this matter before the Office of Administrative Courts. Nothing herein however shall be construed to prohibit Respondent from contesting the NOC.
- 9. Transfer of Ownership and Management Functions of College Pharmacy. Neither Thomas W. Bader nor any members of his family will be beneficial owners of any of the shares of stock of which the ESOP will be the record owner. Neither Thomas W. Bader nor any member of his family, by blood or marriage, shall be employed by College Pharmacy or it successor(s) in any capacity, including as a consultant. All business operations and

management functions of College Pharmacy have been transferred by Thomas W. Bader to an individual or individuals other than himself or a family member.

FINE. Respondent shall pay a fine to the State of Colorado in the amount of \$250,000.00 payable in four equal installments of \$62,500, the first such payment on the date of transfer of CPI stock into the ESOP and the remaining three payments 30, 60 and 90 days thereafter:

# 11. Other Requirements.

- (a) For a period of seven (7) years from the date of this Final Agency Order, College Pharmacy or its successor(s) (hereafter College Pharmacy means College Pharmacy or any of its successor(s)) Pharmacist Manager(s) must be approved by the Board which approval shall not be unreasonably withheld. In the event that a Pharmacist Manager candidate is not approved by the Board, College Pharmacy shall have 24 hours form its receipt of the notice of disapproval to appoint another Pharmacist Manger and seek approval of him/her.
- (b) For a period of seven years (7) from the date of this Final Agency Order, the Pharmacist Manager shall submit quarterly affidavits to the Board on the fifteenth (15th) days of January, April, July and October of each year this Order is in effect averting the following:
  - That during the previous quarter, College Pharmacy did not procure, dispense, distribute, or otherwise introduce into interstate commerce any unapproved new i) drug.
  - That during the previous quarter, College Pharmacy's distributions did not exceed the 10% casual sale limit or the amount as may be later specified in Colorado ii)
  - That during the previous quarter, College Pharmacy neither dispensed nor procured human growth hormone obtained from any source other than a source or iii) sources approved by the Federal Food and Drug Administration ("FDA");
  - That during the previous quarter, College Pharmacy did not dispense human growth hormone for indications other than those indications for which the FDA iv) has approved the use of human growth hormone;
  - That during the previous quarter, all prescriptions dispensed from College Pharmacy have been dispensed pursuant to valid patient-specific orders; and v)
  - That during the previous quarter College Pharmacy did not advertise, market or promote human growth hormone for anti-aging, bodybuilding or body fat vi) reduction or any use other than those allowed under federal law or rule.
- (c) College Pharmacy shall fully comply with all Colorado Pharmacy Laws, Board Rules and Regulations and any other State and Federal Laws related to pharmacies and the practice of pharmacy and the terms of this Final Agency Order.

- 12. Future Violations. Should a substantive or material violation of §§12-22-101 et seq., C.R.S., the Pharmaceuticals and Pharmacist Act, or Pharmacy Board Rules at 3 CCR 719-1 (3/31/06) committed by College Pharmacy, in the of seven year (7) period from the date of this Final Agency Order, be established at a hearing before an Administrative Law Judge or other tribunal with jurisdiction to determine such, the penalty for such violation shall be other tribunal with jurisdiction to determine such, the penalty for such violation shall be revocation of College Pharmacy's registration as a prescription drug outlet and College Pharmacy waives any right to contest or challenge such penalty.
- 13. Dismissal of Pending Action. This Final Agency Order will fully and finally resolve all pending and potential disciplinary actions against the registration of College Pharmacy through October 19, 2007. Upon completion of the transfer of stock as described in Paragraph seven (7) hereof, the Board shall move to dismiss Case No. PH 2007-0003 as to Paragraph seven (7) hereof, the Board shall move to dismiss Case No. PH 2007-0003 as to January 15, 2008, or the Respondent fails to comply with the terms of paragraphs 7 or 8 January 15, 2008, or the Respondent fails to comply with the terms of paragraphs 7 or 8 hereof, the Board, in its sole discretion, may declare this Stipulation and Final Agency order to be null and void and set the NOC for hearing Nothing in this Final Agency Order is intended to, or has the effect of restricting the Board's right or ability to enforce this Final Agency Order through administrative or Court action or to bring any action in the event that Agency Order through administrative or Court action or to bring any action in the event that College Pharmacy is engaging in any act or practice over which the Board has jurisdiction, or affects any other Final Agency Order as to it or any Final Agency Order as to Thomas W.
- 13. Advisements and Waivers. Respondent enters into this Final Agency Order freely and voluntarily, after the opportunity to consult with legal counsel of its own choosing. Respondent acknowledges that it has waived the following rights:
  - a. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and
  - b. to any of the rights set forth in CRS §24-4-105; and
  - c. to appeal or otherwise challenge this Final Agency Order.

# 14. Acknowledgments.

- a. Respondent has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel, that it understands its legal consequences and agrees that none of its terms or conditions are unconscionable. Respondent is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent further acknowledges that he is not entering into this Final Agency Order under any duress.
- b. Nothing herein is intended to stifle the preparation and dispensing of any compounded drugs which will not be deemed unapproved new drugs for the purposes of this final Agency Order.

- 15. Violations. Time is of the essence in this Final Agency Order. Respondent shall take all appropriate steps to comply fully with this Final Agency Order. Respondent acknowledges and agrees that any violation of this Final Agency Order shall be presumed a willful violation of a lawful Board order and in any hearing concerning any violation of this order, College shall have the burden to prove the violation was not willful. The pendency of any litigation arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Final Agency Order.
- 16. <u>Integration and Severability</u>. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.
- 17. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
- 18. <u>Effective Date.</u> This Final Agency Order shall become effective upon signature by a Board representative.

#### ACCEPTED AND AGREED:

| Respondent                               |                               |
|--|-------------------------------|
| College Pharmacy                         |                               |
| Com Bader                                |                               |
| Ву:                                      |                               |
| Its                                      |                               |
| Subscribed and sworn to before me in the | ne County of Elloso, State of |
| Colorado, this 14th day of December 200  | 7, by .                       |
| MY COMMISSION EXPIRES<br>05/22/2010      | Sandy Attende Nolar Public    |
| My Commission expires:                   | NOTARY                        |
|  | PUBLIC 8                      |

| FINAL  | AGENCY ORDER   |
|--|--|
| WHEREFORE, the within Stipulati  | on and Final Agency Order is approved, accepted,   |
| and hereby made an order of the Board,   | 1  |
| HILL HELEDY HEADE AN OLDER OF HEL DOMEST.  | <b>3</b>   |
| DONE AND EFFECTIVE   | his day of 2007.   |
|  | State Board of Pharmacy  |
| N SEC  |  |
|  | BY:  |
| , a ä .  | WENDY ANDERSON Program Director  |
| APPROV   | ED AS TO FORM  |
| Altorneys for Respondent   | Attorneys for State Board of Pharmacy  |
| Duane Mords, LLC.<br>Attorneys at Law  | JOHN W. SUTHERS Attorney General   |
| HOWARD M. HOFFMANN<br>FREDERICK R. BALL  | JACK M. WESOKY, #5001* JOANNA LEE KAYE, #20486* Assistant Attorneys General                                  |
| 227 West Monroe Street, Suite 3400   | Assistant Attorneys Ochura   |
| Chicago, Illinois 60606<br>Telephone: (312) 499-6700<br>Pax: (312) 499-6701      | 1525 Sherman Street, 5th Floor<br>Denver, Colorado 80203<br>Telephone: (303) 866-6170<br>FAX: (303) 866-5690 |
| MARLASH: TORRES, #7986   |  |
| Attorneys for Respondent   | *  |
| 1700 Broadway, Suite 2720<br>Denyer, Colorado 80290<br>Telephone: (303) 830-8685 | *Counsel of Record   |

#### FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an order of the Board.

DONE AND EFFECTIVE this 18 May of Recember 2007.

State Board of Pharmacy

**Program Director** 

APPROVED AS TO FORM

Attorneys for Respondent

Attorneys for State Board of Pharmacy

Duane Morris, LLC. Attorneys at Law

JOHN W. SUTHERS Attorney General

HOWARD M. HOFFMANN

FREDERICK R. BALL

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1700 Broadway, Suite 2720

Denver, Colorado 80290 Telephone: (303) 830-8885

FAX: (303) 830-8890

\*Counsel of Record

### **CERTIFICATE OF SERVICE**

This is to certify that I have duly served the within STIPULATION AND FINAL

AGENCY ORDER upon all parties herein by depositing copies of same in the United

States mail, first-class postage prepaid, at Denver, Colorado, this [7th] day of Docombo (2007) addressed as follows:

Howard M. Hoffman, Esq. Frederick R. Ball, Esq. Duane Morris, LLC 227 West Monroe Street, Suite 3400 Chicago, IL 60606 College Pharmacy Attn: Jerry Simon Gillick, RPH 3505 Austin Bluffs Parkway Colorado Springs, CO 80918

Charles H. Torres, Esq. 1700 Broadway, Suite 2720 Denver, CO 80290

And through interagency mail to: Jack M. Wesoky Joanna Lee Kaye Assistant Attorneys General

(Vic Johnson



**Division of Registrations** Rosemary McCool Director

**State Board of Pharmacy** Wendy Anderson Program Director

Bill Ritter, Jr. Governor D. Rico Munn Executive

Director

April 10, 2009

College Pharmacy Attn: Jerry Simon Gillick, RPH 3505 Austin Bluffs Parkway Colorado Springs, CO 80918

RE: Stipulation and Final Agency Order, effective 4/10/09 Case #2009-0639 and Case #2009-1779

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE REGISTRATION OF COLLEGE PHARMACY, PDO #240000038, IN THE STATE OF COLORADO AS A PRESCRIPTION DRUG OUTLET,

Dear Mr. Gillick:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) in the above mentioned matter, which became effective April 10, 2009.

If you have any questions, or require additional information, please contact the Board's office.

Respectfully,

FØR THE COLORADO BOARD OF PHARMACY

Tia Johnson

Complaint Analyst

Enclosure

cc: File

Brian D. Hector, Esq. & Patrick D. Conner, Esq. Morgan Lewis, 1111

Pennsylvania Avenue, NW, Washington, DC 20004

Jack M. Wesoky, Joanna Lee Kaye, Assistant Attorneys General, Office of

the Attorney General



#### BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Board Case Nos. 2008-0569, 2009-0639 and 2009-1779

#### STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE REGISTRATION OF **COLLEGE PHARMACY**, **PDO# 240000038**, IN THE STATE OF COLORADO AS A PRESCRIPTION DRUG OUTLET,

Respondent Pharmacy.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and College Pharmacy, Inc., d/b/a College Pharmacy ("Respondent Pharmacy") to resolve all matters pertaining to Respondent Pharmacy in Case Nos. 2008-0569, 2009-0639 and 2009-1779, as follows:

#### FINDINGS AND CONCLUSIONS

- 1. The Board has jurisdiction over Respondent Pharmacy, its registration as a prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmacists and Pharmaceuticals Act at Title 12, Article 22, C.R.S.
- 2. Respondent Pharmacy was originally registered as a prescription drug outlet in the State of Colorado in 1974, and has been so registered at all times relevant to this disciplinary action.
- 3. Respondent Pharmacy's address of record with the Board is College Pharmacy, 3505 Austin Bluffs Parkway, Ste. 101, Colorado Springs, Colorado 80918.
- 4. Respondent Pharmacy admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

#### Board Case No. 2008-0569

5. On December 18, 2007, Respondent Pharmacy entered into a Stipulation and Final Agency Order with the Board in OAC Case No. PH 2007-0003, Board Case No. 2008-0569 ("2007 Stipulation," attached hereto). In the 2007 Stipulation, Respondent Pharmacy agreed, inter alia, to the following:

- a. That Respondent Pharmacy would submit quarterly affidavits averring that during the previous quarter, Respondent Pharmacy did not
  - i) dispense human growth hormone for indications other than those indications for which the FDA has approved the use of human growth hormone, or
  - ii) dispense any prescriptions without valid patient-specific orders;
- b. That Respondent Pharmacy shall fully comply with all Colorado pharmacy laws, Board rules and regulations, any other state or federal laws related to pharmacies and the practice of pharmacy, and the terms of the 2007 Stipulation; and
- c. That future violations, if established at hearing, would result in revocation of Respondent Pharmacy's registration as a prescription drug outlet.

### Board Case No. 2009-0639

6. In or about May 2008, during a routine audit of Respondent Pharmacy by Board inspectors, it was discovered that in April of 2008 Respondent Pharmacy had purchased and received human growth hormone (HGH), a prescription drug and controlled substance under Colorado law, from a source that was not a registered prescription drug wholesaler in Colorado. Such conduct was a substantive or material violation of §§12-22-125 (1)(c)(i),(ii) and (iii), and 12-22-125 (1)(k) and (m), C.R.S. Board Rule 1.00.24, and a substantive violation of the 2007 Stipulation.

#### Board Case No. 2009-1779

- 7. In or about May 2008, during a routine audit of Respondent Pharmacy by Board inspectors, it was discovered that a veterinarian in Illinois telephonically ordered HGH from Respondent Pharmacy on a new prescription order dated March 31, 2008, and the veterinarian was listed as both the prescribing practitioner and the patient. Pursuant to the new prescription order, Respondent Pharmacy dispensed the HGH to the Illinois veterinarian. Such conduct was a substantive or material violation of §§ 12-22-125 (1)(c)(i)(ii) and (iii), 12-22-125 (1)(k) and (m), C.R.S., Board Rules 1.00.11 and 3.00.20, and a substantive violation of the 2007 Stipulation.
- 8. The Colorado statutes and Board rules relevant to the subject matter of this Final Agency Order state as follows:

### Colorado Revised Statutes

### 12-22-125. Unprofessional conduct - grounds for discipline.

- (1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:
- (c) Has violated:
  - (I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;
  - (II) The lawful rules of the board; or
  - (III) Any state or federal law pertaining to drugs.
- (k) Has failed to meet generally accepted standards of pharmacy practice...
- (m) Has violated any lawful board order...
- 12-22-125.2. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

### **Pharmacy Board Rules**

- 1.00.11 A pharmacist shall at all times conduct his/her profession in conformity with all federal and state drug laws, rules and regulations; and shall uphold the legal standards of the current official compendia.
- 1.00.24 A prescription drug outlet shall ensure that all prescription drugs and controlled substances are procured from another entity or person registered by the Colorado State Board of Pharmacy. Any drug designated as an Investigational New Drug from the Federal Food and Drug Administration is exempt from this requirement provided the research requirements for the receipt of the product are followed and it meets the requirements of CRS 12-22-128(2).
- 3.00.20 Medical Need. No licensee or registrant shall compound, dispense, deliver or distribute any drug to any person in such quantity or in any situation where the licensee or registrant knows or reasonably should know said drug has no recognized medical utility or application. Violation of this rule shall constitute prima facie proof of violation of CRS 12-22-125.

\* \* \*

9. The Board further finds and concludes, and Respondent Pharmacy agrees, that based upon the above-described stipulated violations of the Pharmaceuticals and Pharmacists Act the following disciplinary action is just and appropriate under the circumstances.

### DISPOSITION 1

10. Transfer of Ownership and Management Functions. Neither Thomas W. Bader nor any members of his family will be owners of any of the shares of stock of Respondent Pharmacy at any future time, or obtain any other ownership interest in Respondent Pharmacy. Neither Thomas W. Bader nor any members of his family, by blood or by marriage, shall be employed by Respondent Pharmacy or its successor(s) in any capacity, including as a consultant. All ownership, business operations and management functions of Respondent Pharmacy have been transferred by Thomas W. Bader to an individual or individuals other than himself or a family member, or to an entity in which he or any family member has no ownership, right of ownership, control or right of control.

#### **Seven Years Probation and Terms**

- 11. <u>Seven Years Probation</u>. Respondent's registration as a prescription drug outlet in the State of Colorado shall be placed on probation for a period of SEVEN (7) YEARS, commencing from the effective date of this Final Agency Order. Credit toward satisfying the period of probation shall be given only during such periods of time that Respondent is in total compliance with all provisions of this Final Agency Order.
- 12. <u>Discontinuance of any dealings in HGH</u>. For a period of seven (7) years from the date of execution of this Final Agency Order, Respondent Pharmacy shall discontinue the procurement, purchase, sale, distribution, dispensing, transferring or handling ("handling") of HGH, and shall not resume handling of HGH during the period of probation Notwithstanding the foregoing, Respondent Pharmacy shall be permitted to dispose of its HGH on hand by returning same to the distributor(s) from whom it procured the HGH unless it was procured from an unregistered source, in which case such HGH shall be destroyed.

No subsidiary, related company or entity of Respondent Pharmacy shall handle HGH during the period of probation provided herein.

13. <u>Transfer of Ownership</u>. For a period of seven (7) years from the date of execution of this Final Agency Order, if ownership of Respondent Pharmacy is transferred, such new owner may petition the Board to handle HGH. Such petition shall be granted or denied in the sole discretion of the Board.

<sup>&</sup>lt;sup>1</sup> Hereafter "Respondent Pharmacy" means College Pharmacy or any of its successor(s).

- 14. <u>Board Approval of Pharmacist Manager</u>. For a period of seven (7) years from the date of execution of this Final Agency Order, Respondent Pharmacy's Pharmacist Manager(s) must be approved by the Board which approval shall not be unreasonably withheld. In the event that a Pharmacist Manager candidate is not approved by the Board, Respondent Pharmacy shall have 24 hours from its receipt of the notice of disapproval to appoint another Pharmacist Manager and seek approval of him/her.
- 15. <u>Quarterly Affidavits</u>. For a period of seven years (7) from the date of execution of this Final Agency Order, the Pharmacist Manager of Respondent Pharmacy shall submit quarterly affidavits to the Board on the fifteenth (15<sup>th</sup>) days of January, April, July and October of each year this Final Agency Order is in effect averring the following:
  - a. That during the previous quarter, Respondent Pharmacy did not procure, dispense, distribute, or otherwise introduce into interstate commerce any unapproved new drug in violation of state or federal laws related to the practice of pharmacy or compounding;
  - b. That during the previous quarter, Respondent Pharmacy's distributions did not exceed the 10% casual sale limit or the amount as may be later specified in Colorado law;
  - c. That during the previous quarter, Respondent Pharmacy did not handle any HGH; and
  - d. That during the previous quarter, all prescriptions dispensed from Respondent Pharmacy have been dispensed pursuant to valid patient-specific orders.
- 16. <u>Compliance</u>. Respondent Pharmacy shall fully comply with all Colorado pharmacy laws, Board rules and regulations, any other state and federal laws related to pharmacies and the practice of pharmacy, and the terms of this Final Agency Order.
- 17. Future Violations Penalty. Nothing in this Final Agency Order is intended to or has the effect of restricting the Board's right or ability to enforce this Final Agency Order through administrative or Court action or to bring any action in the event that Respondent Pharmacy is engaging in any act or practice over which the Board has jurisdiction, or affects any other Final Agency Order as to Respondent Pharmacy except as otherwise provided herein. In the event that Respondent Pharmacy fails to comply with the any terms of this Final Agency Order, the Board, in its sole discretion, may declare this Final Agency Order to be null and void and proceed with commencement of disciplinary action by filing a Notice of Charges against Respondent Pharmacy. Should a substantive or material violation of §§12-22-101 et seq., C.R.S., the Pharmaceuticals and Pharmacists Act, or Board Rules at 3 CCR 719-1 by Respondent Pharmacy during the probationary period set forth herein be established at a hearing before an Administrative Law Judge or other tribunal with jurisdiction to determine such, the penalty for such violation shall be revocation of Respondent Pharmacy's registration as a prescription drug outlet and Respondent Pharmacy waives any right to contest or challenge such penalty.
- 18. <u>Incorporation of Terms of 2007 Stipulation Herein: Discharge of 2007 Stipulation.</u> All terms and obligations of the 2007 Stipulation with which Respondent Pharmacy has not

already complied are incorporated herein and Respondent Pharmacy is discharged from the 2007 Stipulation as of the date of execution of this Final Agency Order. This Final Agency Order shall incorporate and encompass all remaining requirements of the 2007 Stipulation, and supersedes the 2007 Stipulation with respect to Respondent Pharmacy's term of probation.

- 19. Advisements and Waivers. The undersigned authorized representative of Respondent Pharmacy acknowledges that Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after the opportunity to consult with legal counsel of its own choosing. Respondent Pharmacy, through its undersigned authorized representative, acknowledges that Respondent Pharmacy has the following rights:
  - a. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and
  - b. to any of the rights set forth in CRS §24-4-105; and
  - c. to appeal or otherwise challenge this Final Agency Order.

Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

- 20. Acknowledgments. The undersigned authorized representative of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel, that Respondent Pharmacy understands the legal consequences of this Final Agency Order and agrees that none of its terms or conditions are unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.
- 21. <u>Discharge.</u> Discharge from Respondent Pharmacy's probationary period and the requirements of Respondent Pharmacy's probation must be requested in writing by Respondent Pharmacy. The Board will consider any request for discharge during the ordinary course of business. In any request for discharge it shall be Respondent Pharmacy's sole responsibility to establish, through written and other documentation, that it has met all terms and conditions of this Final Agency Order. Respondent Pharmacy's probation shall continue until formally discharged by the Board by way of Board order.
- 22. Violations. Time is of the essence in this Final Agency Order. Respondent Pharmacy shall take all appropriate steps to comply fully with this Final Agency Order. Through its undersigned authorized representative, Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall be presumed a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its

registration. In any hearing concerning any violation of this Final Agency Order, Respondent Pharmacy shall have the burden to prove the violation was not willful. The pendency of any litigation arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

- 23. <u>Integration and Severability</u>. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.
- 24. <u>Effect of Order</u>. This Final Agency order fully and finally resolves Board cases 2009-639, 2009-1779 and 2008-569 which cases were pending against Respondent's registration through March 19, 2009.
- 25. <u>Public Record</u>. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
- 26. <u>Effective Date</u>. This Final Agency Order shall become effective upon signature by a Board representative.

| ACCEPTED AND AGREED:  |  |  |
|---|--|--|
| College Pharmacy  |  |  |
| By:   | .x   |  |
| Title: PRESIDENT  |  |  |
| Subscribed and sworn to before me in the Colorado, this 4th day of 4000 2009, | County of EI Paso, State of by Rachel Christopher. |  |
| MY COMMISSION EXPIRES 05/22/2010 My Commission expires:                       | Sandy Distance Public                              |  |
|   | NOTARY DUBLIC O                                    |  |

#### FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an order of the Board.

DONE AND EFFECTIVE this 10th day of Oppel 2009.

State Board of Pharmacy

BY: Word Carola WENDY ANDERSON

Program Director

#### APPROVED AS TO FORM

Attorneys for Respondent Pharmacy

Attorneys for State Board of Pharmacy

MORGAN, LEWIS & BOCKIUS, LLP

Attorneys at Law

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Attorney General

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JOANNA LEE KATE, #20486\* Assistant Attorneys General

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1525 Sherman Street, 5th Floor

Denver, Colorado 80203

Telephone: (303) 866-6170

FAX: (303) 866-5690

\*Counsel of Record

### **CERTIFICATE OF SERVICE**

This is to certify that I have duly served the within STIPULATION AND FINAL AGENCY ORDER upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 10th day of 2009, addressed as follows:

Brian D. Hector, Esq.
Patrick D. Conner, Esq.
Morgan Lewis
1111 Pennsylvania Avenue, NW
Washington DC 20004

And through interagency mail to:

Jack M. Wesoky Joanna Lee Kaye Assistant Attorneys General

### **NEVADA STATE BOARD OF PHARMACY**

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE CORPORATION

FEE \$500.00 (non-refundable and not transferable)
Application must be printed legibly

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

| application or subsequent revocation of the license issued          | and is a violation of the laws of the State of Nevada.            |
|---|---|
| New Pharmacy Ownership Change N                                     | Name Change Location Change<br>ense number if making changes: PH) |
| GENERAL INFORMATION   |   |
| Pharmacy Name: Med Shop for of Care                                 |   |
| Physical Address: 470 E Coop Z-P/                                   |   |
| Mailing Address:  |   |
| City: Longueu State:  | Z= Zip Code: <u>75605</u>   |
| City: State: State: State:  | ax Number: <u>203 - 234 - 106 z</u>                               |
| Toll Free Number: 800 847 6762                                      |   |
| · · · · · · · · · · · · · · · · · · ·                               | Vebsite:  |
| E-mail: declarage Med Shartan W<br>Managing Pharmacist: Dec Drewing | License Number: <u>35/77</u>                                      |
|   |   |
| Hours of Operation:   |   |
| Monday thru Friday <u>S</u> am <u>b</u> pm                          | Saturdayampm  |
| Sundayampm  | 24 Hours  |
| TYPE OF PHARMACY  | SERVICES PROVIDED   |
| ☐ <del>K</del> etail  | ☐ Off-site Cognitive Services                                     |
| ☐ Hospital (# beds)   | ☑ Parenteral  |
| ☐ Internet  | ☐ Parenteral (outpatient)   |
| ☐ Nuclear   | ☐ Outpatient/Discharge  |
| √ Out of State  | ☐ Mail Service  |
| ☐ Ambulatory Surgery Center   | ☐ Long Term Care  |
| Do- and Horo Outh   |   |
| Board Use Only  | 356 Amount: 5'00,66   |
| Pacaivad: APR 0 8 2009 Chack Number:                                | 356 Amount: 5'00,00   |

### OWNERSHIP IS A CORPORATION State of Incorporation: Texas Parent Company if any: Corporation Name: Med Shop Total Care INC Mailing Address: 470 & Loop 281 Telephone: 903-234-0080 Fax: 803-234-1062 License Contact Person: Dec Townray Professional Compliance Contact Person: Dec Dougland Ownership Information – Complete Section 1 or 2 Do not use N/A in this section – Section 1 or 2 must be completed. Section 1: List the corporations four largest shareholders: (Name and percentage of ownership) 1. Pet Donning 2. San Donning %: 5m 3. \_\_\_\_\_\_\_ Section 2: If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K. Date of Incorporation: Registration number issued: Stock Exchange: List any physician shareholders and percentage of ownership: If corporation is a subsidiary, list name and state of incorporation of the parent corporation and include a list officers.

Within the last five (5) years:

| 1)                       | Has the firm or any owner(s), shareholder(s) with at least 10% interest, off or director(s) thereof, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?  |  |
|--------------------------|--|--|
| 2)                       | Has the firm or any owner(s), shareholder(s) with at least 10% interest, off or director(s) thereof, ever been denied a license, permit or certificate of registration?  | icer(s)<br>Yes □ No 뫁~                   |
| 3)                       | Has the firm or any owner(s), shareholder(s) with at least 10% interest, off or director(s) thereof, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry?  | icer(s)<br>Yes □ No                      |
| 4)                       | Has the firm or any owner(s), shareholder(s) with at least 10% interest, off or director(s) thereof, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?   | icer(s)<br>Yes □ No 🗗                    |
| 5)                       | Has the firm or any owner(s), shareholder(s) with at least 10% interest, offi or director(s) thereof, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?  | icer(s)<br>Yes □ No 🖭                    |
| attach                   | answer to any question 1 through 5 is "yes", a signed statement of explanat<br>ned. Copies of any documents that identify the circumstance or contain and<br>er disposition may be required.   |  |
| corre                    | by certify that the answers given in this application and attached documenta<br>ct. I understand that any infraction of the laws of the State of Nevada regula<br>tion of an authorized pharmacy may be grounds for the revocation of this pe  | ating the                                |
| under<br>correc<br>emplo | e read all questions, answers and statements and know the contents thereof<br>penalty of perjury, that the information furnished on this application are true<br>ot. I hereby authorize the Nevada State Board of Pharmacy, its agents, serv<br>byees, to conduct any investigation(s) of the business, professional, social a<br>pround, qualification and reputation, as it may deem necessary, proper or de | e, accurate and<br>vants and<br>nd moral |
| Signa                    | fat Downing 3/19/09 ture of owner or executive officer Date  | <u> </u>                                 |
| Par<br>Print o           | Downsug Pres.  |  |

### CORPORATE STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I further acknowledge and understand that the corporate officers may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy or operation of a pharmacy in Nevada.

I further acknowledge and understand that upon the change of managing pharmacist in the pharmacy, the corporation must assure that an accountability audit of all controlled substances shall be performed jointly by the departing managing pharmacist and the new managing pharmacist.

Signature

Date



# Neuada State Board of Pharmacy

431 W. PLUMB LANE • RENO, NEVADA 89509 (775) 85C-1440 • 1-800-364-2081 = FAX (775) 650-1444 E-mail: charmacy@pharmecy.mx.gov • Wabsite: bop.nv.gov

## Must be completed and returned with application.

### PHARMACY LICENSE VERIFICATION

|  | Loop ZZ)   |  |  |   |
|--|--|--|--|---|
| hereby authorize the<br>tate Board of Pharm  | Tolde Born   | Od Stern   | to fu  | rnish to the Nevada   |
| tate Board of Pharm<br>ignature of Applicant   | acy, the information,  | requested below  | N.   |   |
|  |  |  |  |   |
| THIS FOR   | RM MUST BE FORW<br>LICENSING AGENO<br>DO NOT WRITE   | Y FOR COMPL  | ETION  | STATE   |
| License Number   | License Status   | Date License Is  | ***************************************  | Detail  |
| 16131  | Active   | 08/23/94   | saueu  | Date License Expire   |
| s this license been cumbered in any way  | ✓ ☐ Revoked ☐ Suspended  | nbrance: (if an  | ed 🔲 l   | 08/31/09<br>Limited   |
| is this license been cumbered in any way  Yes No attached letter   | ☐ Suspended ☐ Please attach c  | nbrance: (if an<br>Surrender<br>Restricted<br>opies of any pert  | ed 🔲 I   | Limited Probation   |
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| as this license been accumbered in any way  No  No  e attached letter  USE REVERSE SIL  As the applicant been stribution of controller as the applicant furnis plications made in contribution? (if yes, please explain)   | DE OF THIS FORM For convicted of any fed substances? (If ver shed any false or fraction mection with drug rease explain) See at fithe applicant results  | nbrance: (if an Surrender Surrender Discovered Periode Description of any periode Description of any distribution of a please explaint of the discovered Description of the discovered Des | inent legalinent legalinent legalines legaline | imited Probation I documents  NECESSARY  attached lette  Yes No     |
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| as this license been cumbered in any way    Yes    No  | DE OF THIS FORM For convicted of any fed substances? (If version with drug rease explain) See attached lettersing requirements.  | nbrance: (if an Surrender Surrender Discontinuo Restricted opies of any perton Research Surrender Description Surrender Description Surrender Description Descript | inent legalinent legalinent legalines legaline | imited Probation I documents  NECESSARY  attached lette Yes No      |

### BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY.

Petitioner.

NOTICE OF INTENDED ACTION

٧.

**AND ACCUSATION** 

WALGREENS #05295, Certificate of Registration #PH01687, Respondent.

Case No. 08-076-PH-N

COMES NOW Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, and makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

١.

The Nevada State Board of Pharmacy has jurisdiction over this matter because Respondent Walgreens #05295 is a pharmacy licensed by the Board located at 750 North Virginia Street, Reno, Nevada.

11.

On or about October 22, 2008, Enrique Ortiz suffered a work-related injury resulting in an open fracture to the small finger of the left hand. He was subsequently taken to the Concentra Medical Center where Mr. Ortiz was treated by Dr. Mikel Meyer. Dr. Meyer dressed the wound and provided Mr. Ortiz with a bottle of cephalexin 500 mg. tablets and a prescription for Vicodin. Mr. Ortiz was referred to a hand surgeon but the surgeon was not immediately available so Mr. Ortiz went to Renown Medical Center where he was seen by Dr. S. Shepherd. Dr. Shepherd wrote additional prescriptions for

Mr. Ortiz for Vicodin and Keflex. The following day, Mr. Ortiz's daughter, Angela Ortiz, copied the prescriptions written by Dr. Shepherd and the prescription for Vicodin from Concentra onto one piece of paper and faxed them to Walgreens #05295 from her workplace at Sparks Pediatrics. The fax was received by Walgreens #05295 on October 23, 2008 and was processed that same day.

III.

The Concentra Vicodin prescription was scanned into the pharmacy computer by pharmaceutical technician Valerie Gonzalez. Data for the prescription was then input into the pharmacy computer by pharmaceutical technician Harpret Singh. Upon completion of data entry, the prescription information, including a scanned image of the fax, was sent to a pharmacist's screen for review. During that review the reviewing pharmacist, Deborah Dorigatti, failed to recognize that the Vicodin fax originated from Sparks Pediatrics and not from the office of the prescribing physician. Pharmaceutical technician Jeannette Pagaling pulled and counted the Vicodin, placed the medication into a container and affixed one label to that container and another to the faxed hard copy. Ms. Pagaling placed the stock bottle, labeled prescription container with the Vicodin, the remaining label set and the labeled hard copy fax into a basket and passed it on to a pharmacist for product review. Carla Knight was the product review pharmacist. During her review, she failed to notice that the fax did not originate from the prescriber's office. Ms. Knight initialed the label on the fax hard copy and then staged the prescription for customer pickup.

The same basic procedure was used for filling the Keflex prescription. Pharmacy technician Valerie Gonzales performed the scan, data entry, counting and labeling while Deborah Dorigatti performed both the data and product reviews. As with the Vicodin prescription, Ms. Dorigatti failed to recognize that the faxed copy of the Keflex prescription did not come from the prescriber's office.

V.

Angela Ortiz picked up the Concentra Vicodin prescription that evening. When she asked Ms. Dorigatti about the other Vicodin and the cephalexin prescriptions, Ms. Ortiz was told that they would not be filled due to substance abuse concerns. Ms. Ortiz also claims that the cephalexin was not filled or dispensed to her that evening, but Ms. Dorigatti gave her no reason why she would not fill the antibiotic for her father. Walgreens #05295 records indicate that the cephalexin prescription was sold three days later, however Ms. Ortiz denies that she or any other family members picked up that prescription. The second Vicodin prescription does not appear to have ever been filled.

VI.

Ms. Ortiz claimed that she was not counseled when Walgreens #05295 dispensed the Concentra Vicodin prescription. Screen shots of Walgreens #05295's computer show that counseling was provided on October 23, 2008 for the cephalexin prescription but it was sold on October 26, 2008. Carla Knight explained that the date of counsel indicated on the screen shot indicates the date of fill not the date of counsel. She was unable to provide Board staff with a date when counseling actually occurred

for either prescription and indicated that the information is purged from the pharmacy computer some time after counseling. Ms. Knight requested an explanation to Walgreens home office to determine if that information could be retrieved. As of the date of this Notice of Intended Action and Accusation Board staff has not received an answer to that question.

### **FIRST CAUSE OF ACTION**

VII.

In failing to counsel Ms. Ortiz regarding Enrique Ortiz's new Concentra Vicodin prescription, Walgreens #05295 violated NRS 639.210(4) and/or NAC 639.707 and/or 639.945(1)(i).

### SECOND CAUSE OF ACTION

VIII.

In failing to maintain accurate counseling records, specifically Mr. Ortiz's cephalexin prescription that showed it was counseled three days before it was dispensed, Walgreens #05295 violated NRS 639.210(4) and/or NAC 639.708(1)(a) and/or (b) and/or 639.945(1)(i).

### THIRD CAUSE OF ACTION

IX.

In owning and operating the pharmacy in which the violations occurred, Walgreens #05295 violated NRS 639.210(4) and/or NAC 639.945(1)(i) and/or (2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of the Respondents.

Signed this 24th day of April, 2009.

Larry L. Pinson, Executive Secretary Nevada State Board of Pharmacy

### NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

### BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

STATEMENT TO THE RESPONDENT

NOTICE OF INTENDED ACTION

AND ACCUSATION RIGHT TO HEARING

٧.

WALGREENS #05295, Certificate of Registration #PH01687, Respondent.

Case No. 08-076-PH-N

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the board by the Petitioner, Larry L. Pinson, Executive Secretary for the board, alleging grounds for imposition of disciplinary action by the board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

11.

You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. Should you desire a hearing, it is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

The Board has reserved Wednesday, June 3, 2009 as the date for a hearing on this matter at the Airport Plaza Hotel, 1981 Terminal Way, Reno, Nevada. The hour of the hearing will be set by letter to follow.

IV.

Failure to complete and file your Notice of Defense with the board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the board, in its sole discretion, elects to grant or hold a hearing nonetheless.

DATED this 246L day of April, 2009.

Larry L. Pinson, Executive Secretary Nevada State Board of Pharmacy

## BEFORE THE NEVADA STATE BOARD OF PHARMACY NEVADA STATE BOARD OF PHARMACY,

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

ANSWER AND NOTICE OF DEFENSE OF ACTION AND ACCUSATION

WALGREENS #05295
Certificate of Registration #PH01687

Case No. 08-076-PH-N

| Responden | ח |
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COME NOW RESPONDENTS, WALGREENS #05295 (Certificate of Registration #PH01687), and named pharmacists involved in the underlying facts supporting the accusation, to wit DEBORAH DERIGATTI and CARLA KNIGHT, by and through their counsel of record, ROBERT C. GRAHAM, ESQ., of the law firm of ROB GRAHAM & ASSOCIATES, do hereby answer as follows:

- 1. That a hearing on the Notice of Intended Action and Accusation is requested.
- 2. That as to the causes of action asserted, WALGREENS #01687 denies the accusation that counseling was not provided as it is WALGREEN's policy and procedure to counsel all new prescriptions being sold or any and all changes to prescription pursuant to Nevada Revised Statutes and the Nevada Administrative Code.
- 3. WALGREENS delegates the responsibility of counseling to each pharmacist working at the pharmacy and does not conduct counseling itself as an owner of a pharmacy. As such, the First Cause of Action must be dismissed.
- 4. WALGREENS keeps accurate records of counseling. Pharmacists are charged with the responsibility of timely entering counseling information and it is the policy and procedure of WALGREENS that Pharmacists attend to counseling and documentation of the same. WALGREENS trains its Pharmacists on how to timely enter this information and provides its Pharmacists with the necessary training on the system that logs the information. At the demand of the Board, WALGREENS

implemented a "stop screen" to assure that the system reminds the Pharmacist of the counseling and requires the Pharmacist to enter a response as to whether counseling has been provided. The Board's requirement has established this routine that requires a response and the responses are recorded and kept. This instant complaint and asserted causes of action, and the extremely limited time the Board has given WALGREENS to provide records which are in its system is prejudicial to WALGREENS and WALGREENS asserts that the Board did not provide an adequate discovery period and gave inadequate time for the notice of this intended action to search its records and database to provide the documents in question. The Board has a history of such conduct that is intended to prejudice any Respondent from adequately preparing a defense in such matters. As such, as the Board has not provided WALGREENS cnough time to respond and WALGREENS has been prejudiced by the severely limited time to respond and prepare its defense, including the normal and customary time to provide documents in a contested matter, which is procedurally a minimum of thirty (30) days from the date when legal counsel obtains notice of the need for such documents. Additionally, as WALGREENS itself does keep accurate and correct records of counseling, and Pharmacists are properly and adequately trained in policy and procedure relating to counseling and documenting the counseling, WALGREENS asks that the Second Cause of Action be dismissed.

- 5. Should no liability be found for a Pharmacist in this instant action, then WALGREENS cannot as a matter of fact and law be held liable for acts that it did not itself do. Additionally, where policies and procedures and adequate training was present at WALGREENS, it does not have independent liability. The liability of WALGREENS is only derived from the liability of Pharmacists who have acted against governing regulations. To that extent, and assuming no Pharmacists are found liable for actions violating counseling regulations, then the Third Cause of Action must be dismissed against WALGREENS.
- 6. In terms of mitigating factors the Board should consider should a Pharmacist or WALGREENS be found liable are as follows:

- A. This Board is the governing body that required the "stop screen" be added to the WALGREENS system. The "stop screen" requires an entry for counseling be entered before it can be cleared from the system. This is as the Board wanted and required it. If there is a systemic problem with this "stop screen" and the way that it collects data, the Board shares some responsibility in how it has required the "stop screen" to be present in the WALGREENS' system. Should the Board want to modify the system, it needs to understand that such system changes take time and substantial funds to modify. In the past two years, WALGREENS is only aware of approximately two such incidents raising to the level of Board action. In each case, the issue of whether consultation actually occurred was disputed and a language barrier existed in each of the cases.
- B. Respondent WALGREENS hires and retains professional pharmacists and has in place policies, procedures and systems to help its professionals avoid these types of incidents.
  - C. The prescriptions in question were both filled and labeled correctly.
- D. That much of the complaint in this instant action was NOT centered around consulting, but rather a complaint about obtaining access to prescriptions. The gatekeeping activities and concerns of the Pharmacist have been entirely lost in the complaint. The Board investigators have chosen to focus on aspects of the matter that were NOT the actual focus of the complaint by the consumer. In essence, the Board investigators have chosen their own complaint and pursued their own agenda rather than investigating the actual consumer complaint. In doing so, the complaint has been fashioned in such limited time as to provide WALGREENS with inadequate time to fully and appropriately respond.
- E. As to a prior matter that existed with this particular WALGREENS #05295 before the Board, the store had successfully fulfilled a two year probation. The prior incident in question was fundamentally unrelated to counseling and was instead for refilling a prescription more than the authorized times based upon faxes being submitted to the pharmacy from an unauthorized person. As the store was off probation at the time of this incident and as the prior matter was not related to counseling.

this store and this matter should be treated as an entirely new matter without considerable weight being put on the multiplicity of complaints (2) to date.

DATED THIS 20th day of May, 2009.

& ASSOCIATES

ROBERT C. GRAHAM Attorney for Respondents

Nevada Bar No. 4618 7375 W. Peak Dr., #220

Las Vegas, Nevada 89128

rgraham@lawyerswest.net

(702) 255-6161



## Neuada State Board of Pharmacy

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

April 23, 2009

### **CERTIFIED MAIL - RETURN RECEIPT REQUESTED**

Bonnie Brandt, District 4 Pharmacy Manager For Smith's Pharmacy #392 2211 North Rampart Las Vegas, NV 89128

RE:

Nevada Certificate of Registration Number: PH01331

Nevada Board of Pharmacy Case Number: 08-074-PH-N

Dear Ms. Brandt:

Enclosed you will find original copies of the following documents:

- (1) one Notice of Intended Action and Accusation
- (2) one Statement to Respondent
- (3) three Notices of Defense

These documents indicate that a disciplinary matter before the Nevada State Board of Pharmacy has been commenced. Please review these documents carefully, and if you would like a hearing on this matter please complete the Answer and Notice of Defense documents and return two of them to this office within fifteen (15) days of receipt.

As an alternative to a hearing, the investigative committee of the Board can offer you a settlement in this matter. Particularly, the investigative committee offers to present a stipulated agreement in settlement of the present action to the Board for the Board's review and approval.

We have enclosed the Stipulation that would be presented to the Board in lieu of an actual hearing if you choose to accept the Stipulation. The stipulated agreement will be presented to the Board at the June 3<sup>rd</sup>, 2009 public meeting, will be discussed, and will be accepted as presented, rejected as presented, or modified. You will not need to be present when the stipulated agreement is presented to the Board, and you will be notified of the decision of the Board.

Bonnie Brandt, District 4 Pharmacy Manager for Smith's Pharmacy #392 April 23, 2009 Page 2

No action against your license other than acceptance of the stipulated agreement can be taken by the Board unless you are notified and provided the opportunity to appear before the Board at a subsequent meeting. If you would like to accept the above offer for a stipulated agreement, you must sign and date the enclosed Stipulation and return it to this office within fifteen (15) days of the receipt of this letter.

If you would like to discuss the stipulation or if you have any questions, please call me.

Sincerely,

Larry L. Pinson, Pharm.D.

**Executive Secretary** 

LLP:jlw

**Enclosures** 

### BEFORE THE NEVADA STATE BOARD OF PHARMACY

**NEVADA STATE BOARD OF PHARMACY,** 

Petitioner,

NOTICE OF INTENDED ACTION

AND ACCUSATION

SMITH'S PHARMACY #392 Certificate of Registration No. PH01331

٧.

Case No. 08-074-PH-N

Respondent.

COMES NOW Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, and makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

١.

The Nevada State Board of Pharmacy has jurisdiction over this matter because Respondent Smith's Pharmacy #392 (Smith's #392) is a pharmacy licensed by the Board, located at 2200 Highway 50 East, Dayton, Nevada.

II.

Andrea Majerczyk is a female that had been diagnosed with Reflex Sympathetic Dystrophy. On the morning of October 2, 2008 Ms. Majerczyk telephoned Smith's #392 for refills of her prescriptions for klonopin, gabapentin, Elavil, provigil, Effexor, Nexium and six boxes of Actiq. Ms. Majerczyk's friend, Mr. Krepps, went to the pharmacy to pick up Ms. Majerczyk's medications for her later that day. Mr. Krepps was asked for a co-pay of \$1.50 and he thought that was unusual because he never pays a co-pay when picking up Ms. Majerczyk's prescriptions. Mr. Krepps paid the co-pay and delivered the medication to Ms. Majerczyk.

Ms. Majerczyk ingested her daily dosages of each of the medications shortly after receiving them from Mr. Krepps. The following morning Ms. Majerczyk was filling her weekly pill container and noticed that one of the prescription bottles she had received from Smith's #392 did not belong to her. What she thought was her Effexor 75 mg. tablets was actually Patient DS's buproprion SR 150 mg. tablets.

IV.

During the investigation of this matter it was found that a pharmaceutical technician input the refills, printed the label sets and placed them in a basket for eventual filling by a pharmacist. Though the pharmacy staff could not recall this instance, they determined that a label for Patient DS must have printed along with Ms. Majerczyk's labels and when the labels were removed from the printer they were all inadvertently placed in the basket for filling Ms. Majerczyk's prescriptions.

### FIRST CAUSE OF ACTION

٧.

By dispensing a prescription medication to Mr. Krepps for Ms. Majerczyk that was not prescribed for her, but was prescribed for Patient DS, Smith's #392 violated NRS 639.210(4) and/or NAC 639.945(1)(i) and (2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent.

Signed this 23<sup>2</sup> day of April, 2009.

Larry L. Pinson, Executive Secretary Nevada State Board of Pharmacy

### **NOTICE TO RESPONDENT**

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

### BEFORE THE NEVADA STATE BOARD OF PHARMACY

**NEVADA STATE BOARD OF PHARMACY,** 

Petitioner.

٧.

STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING

SMITH'S PHARMACY #392 Certificate of Registration No. PH01331 Case No. 08-074-PH-N

| Respondent. |     |  |
|-------------|-----|--|
| <br>        | - 1 |  |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B, a Notice of Intended Action and Accusation has been filed with the board by the Petitioner, Larry L. Pinson, Executive Secretary for the board, alleging grounds for imposition of disciplinary action by the board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

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You have the right to a hearing before the Nevada State Board of Pharmacy to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. Should you desire a hearing, it is required that you complete two copies of the Answer and Notice of Defense documents served herewith and file said copies with the Nevada State

Board of Pharmacy within fifteen (15) days of receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within.

The Board has reserved Wednesday, June 3, 2009 as the date for a hearing on this matter, if requested, at the Airport Plaza Hotel, 1981 Terminal Way, Reno, Nevada. The hour of the hearing will be set by letter to follow if you choose to have a hearing.

IV.

Failure to complete and file your Notice of Defense with the board and thereby request a hearing within the time allowed shall constitute a waiver of your right to a hearing in this matter and give cause for the entering of your default to the Notice of Intended Action and Accusation filed herein, unless the board, in its sole discretion, elects to grant or hold a hearing nonetheless.

DATED this 23dd day of April, 2009.

Larry L. Pinson, Executive Secretar Nevada State Board of Pharmacy

### BEFORE THE NEVADA STATE BOARD OF PHARMACY,

## NEVADA STATE BOARD OF PHARMACY Petitioner.

٧.

ANSWER AND NOTICE OF DEFENSE

SMITH'S PHARMACY #392 Certificate of Registration No. PH01331 Respondent. Case No. 08-074-PH-N

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

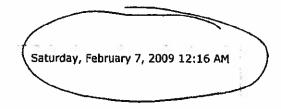
| 2. That, in answer to the  | Notice of Intended A    | action and Accusa | ation, he admits, | denies |
|----------------------------|-------------------------|-------------------|-------------------|--------|
| and alleges as follows:    |                         |                   |                   |        |
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| l hereby declare, under pe | enalty of perjury, that | the foregoing An  | swer and Notice   | e of   |
| Defense, and all facts the |                         |                   |                   |        |
|                            |                         |                   | ·                 | _      |
| DATED this                 | day of                  |                   | , 2009.           |        |
|                            | type or print name      |                   |                   |        |
|                            | for Smith's Pharma      | cy #392           |                   |        |
|                            |                         |                   |                   |        |
|                            |                         |                   |                   |        |



### Request to Appear Before the Nevada State Board of Pharmacy

From: "Henry Miller" <hamilier77@yahoo.com>

To: jwalter@pharmacy.nv.gov Cc: hamiller77@yahoo.com



Dear Madam,

Per our conversation on the morning of February 5th, 2009, I am requesting to appear before the Nevada State Board of Pharmacy for the April 15th or 16th meeting. I am requesting the appearance for the reinstatement of my license to practice pharmacy in the State of Nevada. Thank you in advance for your efforts.

Respectfully,

Henry A. Miller

Terri

775-850-1440

wer Jun 3 cp

#### BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

FINDINGS OF FACT, CONCLUSIONS OF LAW,

AND ORDER

HENRY A MILLER, R.Ph,
Certificate of Registration #PT13722,

V.

Case No. 08-006-RPH-S

| Res | po | nd | len | t. |
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THIS MATTER was heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on June 4, 2008, in Reno, Nevada. The Board was represented by Louis Ling, General Counsel to the Board. Respondent Henry A. Miller appeared and was represented by Erick M. Ferran of Patti, Sgro & Lewis from Las Vegas, Nevada. Based on the presentation of the parties and the public records in the possession and control of the Board, the Board issues the following Findings of Fact, Conclusions of Law, and Order:

### **FINDINGS OF FACT**

- 1. Mr. Miller agreed that the facts alleged in the Notice of Intended Action and Accusation were true and correct. Based upon Mr. Miller's admissions and stipulations, Board Staff did not present any testimony. Mr. Miller testified on his own behalf by way of mitigation and explanation, and he presented the testimony of Larry Espadero from PRN-PRN. Based upon the presentations, admissions, and stipulations of the parties, the Board finds the following to be the facts of the matter.
- 2. In 2007, Mr. Miller was employed as a pharmacist at Smith's Pharmacy #349 (Smiths #349) in Las Vegas, Nevada. Mr. Miller was terminated from his employment at Smiths #349 on August 15, 2007 for taking a newspaper and gum without paying for them. After Smiths #349 terminated Mr. Miller, it conducted an audit of its controlled

substances and ultimately found that for the period of May 2007 through August 15, 2007, Mr. Miller had created 72 fraudulent prescriptions for hydrocodone products accounting for a total of 16,020 dosage units of hydrocodone, the value of which Smiths #349 estimated to be \$3,714.29. Smiths #349 subsequently informed the Board of the results of its audit and its conclusions regarding Mr. Miller's fraudulent actions.

- 3. After Mr. Miller was terminated by Smiths #349, he began working as a pharmacist at Professional Pharmacy, Inc. which does business in Las Vegas as OnePoint Patient Care (OnePoint). OnePoint is a closed-door pharmacy that serves hospice patients and assisted-living residents. While at OnePoint, Mr. Miller began a practice of creating false prescriptions for patients of OnePoint which he then filled and removed for his own use. The false prescriptions were for hydrocodone products and alprazolam 2 mg. tablets. Through this scheme of creating false prescriptions, for the period of October 22, 2007 through March 5, 2008, Mr. Miller removed a total of 19,153 dosage units of hydrocodone products and 2,240 units of alprazolam 2 mg. for his personal use and without lawful authorization therefore.
- 4. On March 31, 2008, Board Staff received a letter from OnePoint by which OnePoint informed the Board of the results of its investigation regarding Mr. Miller. As a result of receiving the letter from OnePoint, on April 3, 2008, the Board's Executive Secretary Larry L. Pinson, Pharm.D. issued a Notice of Immediate and Temporary Suspension of Pharmacist's License, thereby suspending Mr. Miller's pharmacist's license. The suspension notice was served upon Mr. Miller through service upon his attorney on April 7, 2008.
- 5. At hearing, Mr. Miller explained that before he studied pharmacy, he had been a football player at the college level. While playing football, Mr. Miller severely

injured a knee, resulting in subsequent surgeries and chronic and lingering pain. Mr. Miller explained that he began removing hydrocodone products from Smiths #349 and continued the removing of hydrocodone products from OnePoint (and also alprazolam 2 mg.) to self-treat the pain he suffered daily. Mr. Miller explained that he realized that what he was doing was wrong, but once he became accustomed to the hydrocodone and its effects, he could not stop. Mr. Miller testified that he tried to quit several times, but could not. He admitted that he was taking 40 or more dosage units of hydrocodone per day. Mr. Miller began taking the alprazolam 2 mg. to assist him with sleeping and the guilt and anxiety caused by his fraudulent conduct. Mr. Miller also explained that he did not consume all of the thousands of tablets of hydrocodone he had removed from Smiths #349 and OnePoint and was hoarding some of the controlled substances in case he was ever caught.

- 6. Mr. Miller explained that his pain issues persisted and effected his ability to continue to train with weights, although Mr. Miller appeared at the hearing to be extraordinarily muscular. Board members questioned Mr. Miller as to whether he used anabolic steroids or HGH, and Mr. Miller denied doing so. Mr. Miller also denied selling or trading any of the hydrocodone or alprazolam he had unlawfully procured to other people to obtain other drugs, including anabolic steroids or HGH.
- 7. Mr. Espadero testified that Mr. Miller entered the PRN-PRN program in May 2008 and that Mr. Miller appeared to be working well within his substance abuse treatment program. Mr. Espadero stated that it was too early in Mr. Miller's treatment to render an opinion regarding Mr. Miller's future prognosis. Mr. Espadero stated that Mr. Miller's urine samples had all tested negative since Mr. Miller joined the PRN-PRN program, and Mr. Miller testified that he had been clean and sober since entering the

PRN-PRN program. Mr. Miller also testified that he had destroyed all of the hoarded controlled substances.

### **CONCLUSIONS OF LAW**

- 1. The Board has jurisdiction over this matter because Mr. Miller is a pharmacist licensed by the Board.
- 2. In removing controlled substance, namely hydrocodone and alprazolam, from two employing pharmacies without lawful order or authorization therefore, Mr. Miller violated NRS 453.331(1)(d) and (f), 453.336(1), and 639.210(1) and (4) and NAC 639.945(1)(h) and (i).
- 3. In creating false, fraudulent, or deceitful records regarding controlled substances at Smiths #349, including but not limited to false prescriptions and false entries into the Smiths #349 computer system, Mr. Miller violated NRS 4563.331(10(e) and 639.210(1), (4), and (12) and NAC 639.945(1)(h) and (i).
- 4. In charging himself the discounted price of \$55.99 for the false hydrocodone prescriptions he removed from Smiths #349, thus realizing a financial benefit estimated to exceed \$3,700.00, Mr. Miller violated NRS 639.210(1) and (4) and NAC 639.945(h).
- 5. In removing controlled substances, namely hydrocodone products and alprazolam, from OnePoint without lawful order or authorization therefore, Mr. Miller violated NRS 453.331(1)(d) and (f), 453.336(1), and 639.210(1) and (4) and NAC 639.945(1)(h) and (i).
- 6. In creating false, fraudulent, or deceitful records regarding controlled substances at OnePoint, including but not limited to false prescriptions and false entries into the OnePoint computer system, Mr. Miller violated NRS 453.331(1)(e) and 639.210(1), (4), and (12) and NAC 639.945(1)(h) and (i).

### ORDER

Based upon the foregoing, the Board imposes the following discipline:

- 1. Mr. Miller's pharmacist's license (#13722) shall be placed on probation for a period of at least five years from the effective date of this Order, subject to the following terms and conditions:
- a. Mr. Miller's pharmacist's license shall be suspended for a period of at least one year from April 1, 2008, during which time Mr. Miller may not be employed in any business or facility licensed or registered by this Board. Mr. Miller may apply for reinstatement of his pharmacist's license at any time after June 5, 2009 only if:
  - (1) He provides written evidence that he has paid restitution to Smiths #349 and OnePoint in such amounts and under such circumstances as were reasonably acceptable to each pharmacy.
  - (2) He schedules an appearance before the Board at which he would appear with a representative of PRN-PRN. The purpose of the appearance before the Board is to allow the Board the opportunity to ascertain whether Mr. Miller can safely and lawfully return to the practice of pharmacy. At any such appearance, the Board may add additional terms and conditions.
- b. Mr. Miller shall remain compliant with his treatment agreement with PRN-PRN upon such terms and conditions as PRN-PRN shall deem necessary and appropriate.

  Mr. Miller shall comply fully with the terms and conditions required of him by PRN-PRN.

  Mr. Miller's probation shall be for such a term as PRN-PRN determines to be necessary and appropriate. Any violation of Mr. Miller's PRN-PRN agreement shall constitute a violation of this Order.

- c. If and after Mr. Miller's pharmacist's license is reinstated, Mr. Miller may not be employed or serve as a managing pharmacist.
- d. Mr. Miller shall notify his present employer and any potential employers licensed or registered by this Board of the existence and terms of this Order and shall provide a copy of this Order to his employer or potential employer.
- e. Mr. Miller shall provide to PRN-PRN a copy of or notification of any prescription he receives from a physician. If Mr. Miller seeks a prescription for a controlled substance, he shall assure that the physician is notified of this Order before the physician prescribes a controlled substance for Mr. Miller.
- f. PRN-PRN shall notify the Board's office of any breach of his treatment agreement committed by Mr. Miller. The Board's staff shall evaluate and, if it deems necessary, investigate the breach and shall take such action, including seeking additional discipline, as the Board's staff deems appropriate.
- g. PRN-PRN shall notify the Board's office of Mr. Miller's successful completion of his treatment agreement. If Mr. Miller has otherwise complied with the terms of this Order, his probation shall terminate upon the Board office's receipt of the notification from PRN-PRN if such notification is received after the passage of five years from the effective date of this Order. If Mr. Miller completes his treatment agreement with PRN-PRN prior to the passage of five years from the effective date of this Order, then he shall remain on probation until the passage of five years from the effective date of this Order.
- h. Mr. Miller shall comply with all laws relating to the practice of pharmacy, whether state or federal, statute or regulation.
  - i. If Mr. Miller intends to reside outside of Nevada, he must:

- (1) Notify PRN-PRN and the Board in writing at least two weeks before he departs the state;
- (2) Enroll in a substance abuse treatment program sponsored by or affiliated with the board of pharmacy in the state in which he intends to make his residence, if such a program is available. If such a program is unavailable, then Mr. Miller shall attempt to obtain private substance abuse treatment. Mr. Miller shall notify PRN-PRN that he has enrolled in a sister-state program or a private program within two weeks after he has moved to the new state. PRN-PRN shall correspond with the sister-state program or the private program to assure that the program will operate in a manner satisfactory to PRN-PRN. While Mr. Miller is enrolled in a sister-state or private program, his treatment shall be monitored by PRN-PRN, and any violation of the out-of-state program shall constitute a violation of Mr. Miller's treatment agreement with PRN-PRN and this Order.
- j. If Mr. Miller is not able to reasonably enroll in an out-of-state programs pursuant to paragraph (2) above, then he shall notify the Board office and PRN-PRN that of his inability to enroll, and this Order will thereafter be stayed until Mr. Miller either enrolls in an out-of-state program or until Mr. Miller again resides in Nevada and reenrolls in the PRN-PRN program.
- k. Mr. Miller shall be responsible for and shall pay all fees and costs related to his substance abuse treatment pursuant to this Order. A failure to pay any of these fees or costs for treatment shall be deemed a violation of this Order.
- 2. Upon receipt of credible information that Mr. Miller has failed to comply with any term of this Order, the Board's Executive Secretary shall be authorized to

immediately suspend Mr. Miller's license. The Board's Executive Secretary shall also prepare and file such documents as are necessary to allow the Board to impose further discipline, up to and including revocation of Mr. Miller's license. Furthermore, any failure to pay any fine, fee, or cost ordered herein will also result in such legal action as Board staff determines to be necessary to collect the unpaid fine, fee, or cost.

Signed and effective this 30 day of July, 2008.

Barry Boudreaux, President

Nevada State Board of Pharmacy

# **EXECUTIVE SECRETARY REPORT – JUNE 2009**

- A) FINANCIAL REPORT
- **B) INVESTMENT REPORT**
- C) TEMPORARY LICENSES
- D) STAFF ACTIVITIES
  - 1. Meetings
    - a. PT Committee (4/22)
    - b. Telepharmacy/Telemedicine (4/23 & 4/28)

5

- c. NABP Miami
- 2. Legislative Update
  - a. Hillerby Report

### E) REPORT TO BOARD

- 1. Abuse of emergency CII Rx rule
- 2. Ryan Haight Act
- 3. Virginia PMP Hack
- 4. Tech school requirements
- 5. Temporary regulations
- F) BOARD RELATED NEWS
- **G) ACTIVITIES REPORT**

# TEMPORARY LICENSES (Issued since last board meeting)

### ContinueCare of Carson Tahoe

Rhonda Baker

<u>Walgreens</u>

Maree Kiledjian

Smith's

**Michael Stokes** 

LEGISLATIVE ADVOCACY GOVERNMENT RELATIONS

4-24-09

### LEGISLATIVE REPORT

The Nevada Legislature now has just 5 weeks to finish the 2009 session, and with another deadline just passed to move bills from their house of origin, the focus has sharpened on the issues left on the table and the budget choices looming ahead.

The Economic Forum meets this Friday, May 1 and is widely expected to tell the Legislature they have \$600 million less than originally expected. However, the media reports that other shortfalls in the Governor's recommended budget make the total shortfall over \$780 million, and lawmakers and the administration continue to haggle over the federal stimulus package and how it will be used.

This past week the core group of Legislative leaders (who meet privately to discuss the budget and potential tax plans) met with a variety of business leaders from around the state to talk about the budget and ways to fund it. There was general agreement that a broad-based increase was needed, and the likely targets will be potentially doubling the Modified Business (or payroll) Tax and an incremental bump in the sales tax. Individual lawmakers are pushing a corporate net profits tax and a sales tax on services, but both ideas face serious political opposition and would take both time and new resources in the Taxation Department to implement.

Adding to the difficulty of raising even existing rates are the desires of differing factions. Senate Majority Leader Stephen Horsford has expressed concern about the sales tax because of its regressive impacts on the lower income. Senate Minority Leader Bill Raggio and members of his caucus want any increases to sunset in 2011, and any tax plan will need at least two Republican votes in the Senate.

The core group also heard from business leaders that much of their support was contingent on the Legislature making meaningful changes to the unfunded liabilities in the State employee health care and pension plans, as well as reining in salaries and benefits at the local government level. With health care, salaries and pensions consuming the overwhelming majority of the budget, structural changes to these areas must be dealt with to avoid future sessions facing similar budget shortfalls.

The total tax increase is likely to be less than the \$833 million increase passed in 2003- not because of any connection to the size of the hole, but the fear of facing the electorate having passed the new, largest increase in state history. Because of the timing of a threatened gubernatorial veto and the mechanism for an override, the final package must pass out by the Memorial Day weekend. Expect the Legislative cauldron to heat up from a simmer to a full boil just after the May 1 Economic Forum meeting.

While the budget gets the star treatment these days, policy issues continue to move forward and will generate more attention as Sine Die looms. Labor continues to use new found clout to advance their issues, including prevailing wage and significant changes to workers' compensation laws. The variety of proposals on alternative energy and state tax incentives will likely emerge as amendment packages to one or two bills in each house. Lawmakers continue to wrestle with proposals on reforming mortgage lending regulation and home owners' association laws, as well as the complicated Disproportionate Share system that partially reimburses the hospitals that see the largest portion of uninsured patients.

The Governor has only signed 15 bills so far, and how he handles bills like the domestic partner act just passed by the Senate, and a variety of attempts to shift the political pendulum from the Executive to the Legislative branches, will have a major impact on the level of acrimony as the session's end. Lawmakers will do their part to add to the stress with the large number of bills held "hostage" because of their perceived importance to individual legislators and just where their vote may be needed to be leveraged.

LEGISLATIVE ADVOCACY GOVERNMENT RELATIONS

5-8-09

### Legislative Report

The Nevada Legislature is about to enter the 100th day of its 120 session, with the budget and accompanying tax increase bill taking center stage. Friday, May 8 was supposed to see the last major budget close (Higher Education) and set the tone for two weeks of tax discussions and final budget details. As is customary in Carson City, the trains can move quickly from "running late" to "off the rails."

Following the May 1 Economic Forum and the grisly news they delivered, legislators are looking at a tax increase of some \$900 million dollars just to fund the Governor's recommended budget. Even with \$350 million in stimulus funds, they will need to raise close to \$800 million to fund their version of the budget.

The need to have at least two Republican votes for the tax package drove the decision to close the higher education budget last - long the beneficiary of Senator Bill Raggio's protection. Sir Bill and his fellow Republican colleagues are reportedly holding out for a tax number some tens of millions of dollars less than the Democratic majority's. By holding his favorite budget last, Democratic leaders hoped to coax the last millions from Raggio to fund higher education. Raggio reportedly countered with a desire to make cuts in other areas of the budget, including K-12 education, which the Majority has (so far) refused; hence, the latest derailment.

Because of the 120 day calendar and Governor Gibbons' threatened veto of the budget and any tax bill, legislators are forced to change the final schedule. A completed budget and tax plan must be to Gibbons by May 22 (give or take a day) to allow the Legislature time to process the veto override and pass the myriad bills they are holding hostage as leverage for various members' votes. This is the equivalent of laying new track ahead of them, while they rip up the track behind.

Also important for Republicans are a variety of reforms to public employee benefits and pensions. They would like to make incremental increases in the current system that allows employees with 30 years to retire with full pension benefits at any age (25 years for police and fire employees). They would also like to limit the subsidy future retirees would receive for health benefits. While these and other similar changes won't generate significant savings this biennium, they are seen as crucial to addressing the long term liability faced by the State and the exponential yearly increase in the cost of retirees.

These discussions come in a week where legislators made the decision to furlough State employees one day a month, and made similar percentage decreases to K-12 and Higher Ed salary budgets. They also rejected a call from the Governor to make large cuts to existing employee health insurance subsidies, and to cut the subsidies for new retirees and current retirees who become Medicare eligible.

The tax plan is almost certain to include a significant increase in the payroll tax and an increase in the portion of the sales tax used to fund schools. Changes to the mining tax, sin taxes, the insurance premium tax and other existing taxes will be very tempting to lawmakers looking for a quick infusion of cash. This week also saw the introduction of a bill to tax satellite television providers, a small sum to the State but evidence that no stone will go unturned in the hunt for cash. And some Democratic leaders continue to preach the benefits of a sales tax on services or a net profits tax on corporations. (Both of these would require political magic, new bureaucracies, and perhaps most fatal, time to implement.)

Work continues to secure the current tax breaks and incentives for everything from solar energy to large scale shopping destinations. After 90 days of attacking the cost of these incentives to local schools, legislators now seem ready to acknowledge that these tools have been helpful to Nevada and should continue as we look for ways to expand the tax base and economic development. The next derailment will be balancing these against a budget with a floating target; every new hole in the budget will need a new cut or a new source of revenue (see the satellite tax above, certainly not the last "new idea" we will see.)

The most contentious issues are still before us: medical tort reform, major workers' comp overhauls, raiding the coffers of local government, public employee collective bargaining and benefits reform, growth and water, energy, major healthcare bills, and several other issues still waiting in the wings.

May 15 is the deadline for non-exempt bills to pass out of their final committees, and May 22 is the deadline for these bills to pass out of the second house and be sent to the Governor. Because of the new veto override schedule, the last 10 days of this Legislature will be unlike any we have seen. We expect a record number of delays, derailments and even gruesome crashes before the train that is the 2009 Legislature rolls into the station June 1.

LEGISLATIVE ADVOCACY
GOVERNMENT RELATIONS

5-8-09

To:

Larry Pinson, NSBP

From:

Fred Hillerby

Re:

Bill Update and Legislative Report

With deadlines fast approaching, we continue to monitor remaining bills and associated hearings and work sessions. For bills that have been heard and amended, a link is provided to the amended language, if available. There is always a lag between committee actions and publication of changes/amendments; please check back on the Nevada Legislative website (click the highlighted bill number) in a few days to see if a reprint is available. Bills which have been declared "eligible for exemption" or "exempt" have been designated as such because of the bill's potential effect on the executive budget.

May 15 is the deadline for non-exempt bills to pass out of final committees, and May 22 is the deadline for these bills to pass out of the second house. We will do our best to keep you apprised of developments, but as noted in the accompanying Legislative Report, a fast and furious run to the end of the session is expected.

As always, should you have particular concerns or new information that would help Fred in his efforts on your behalf, please don't hesitate to contact us by email or phone.

AB112 (BDR 214) - Legislative Committee on Health Care - (NRS 439B.200) – Establishes provisions relating to public health emergencies.

Bill Text

As Introduced 1st Reprint

Adopted

Amendments

Amend. No.475

Senate Health and Education

May. 06, 2009

03:15

PM

Do pass

AB113 (BDR-86)—Assemblyman Hogan—Revises pravisions relating to the information specified on the label of the container for a prescription drug. 4/10 died

<u>AB123</u> (BDR 215) - Legislative Committee on Health Care – (NRS 439B.200) – Revises provisions governing certain offices of physicians and related facilities and surgical centers for ambulatory patients.

Bill Text As Introduced 1st Reprint Amend. No.328

4/15 – exemption effective.

Upcoming Hearings

Senate Health and Education May. 11, 2009 Upon Adjournment Agenda

AB198 (BDR-29) — Assemblyman-Segerblom — Greates the Deferred Savings Option Program within the Public Employees' Retirement System, 4/10 died

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LEGISLATIVE ADVOCACY **GOVERNMENT RELATIONS** 

AB200 (BDR 469) - Assemblywoman Gansert (& 18 others) - Extends limited immunity from civil-liability to certain medical providers who render gratuitous care under certain circumstances. 4/10 died

AB213 (BDR39) - Assemblyman Anderson & 18 others - Requires the establishment of the Cancer Drug Donation Program.

**Bill Text** 

As Introduced

1st Reprint

**Adopted Amendments** 

Amend. No.459 Amend. No.329

Senate Health and

May. 01, 2009 Upon

Education

Adjournment

pass

AB282 (BDR633) - Assemblywoman Gansert & 12 others - Revises provisions governing the Public Employees' Retirement-System, Died 4/10

AB326 (BDR558) - Denis - Revises provisions governing controlled substances.

**Bill Text** 

As Introduced

1st Reprint

**Adopted Amendments** 

Amend. No.471

**Upcoming Hearings** 

Senate Health and Education

May. 11, 2009 Upon

Adjournment

**Agenda** 

AB331 (BDR1982) - Settelmeyer & 11 others - Provides for the appointment of a Business Ombudsman.

**Bill Text** 

As Introduced

1st Reprint

Adopted Amendments

Amend, No.327

Assembly Ways and Means

May. 04, 2009 03:30 PM

No Action

AB374 (BDR174) -- McClain - Revises previsions relating to the Public Employees' Retirement System: 4/10 died

AB395 (BDR1020) - Provides for workplace relations discussions and agreements for certain state employees.

Bill Text

As Introduced

1st Reprint

Amend. No.518

**Upcoming Hearings** 

May. 12,

Senate Legislative Operations and

2009 01:30 PM Agenda

**Elections** 

AB406 (8DR759) - Gansert & 5 others - Makes various changes relating to the Public Employees' Benefits Program. Died 4/10

AB434 (BDR206) - Cobb & 12 others - Makes various changes concerning the Public Employees' Retirement System: 4/10 died

AB440 (SDR132) - Hardy-&-3 others - Revises provisions governing the reemployment of cortain relired persons under the Public Employees' Retirement System 4/10 died

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LEGISLATIVE ADVOCACY GOVERNMENT RELATIONS

AB442 (BDR176) - Kirkpatrick & 8 others - Revises provisions concerning lobbying.

Bill As Introduced 1st Reprint 2nd Reprint Amend. No.545

Text Amend.No.554

Senate Legislative Operations and Apr. 28, 2009 01:30 No Elections PM Action

AB463 (BDR1057) - Smith - Restricts a department, division or other agency of this State or a local government from employing a person as a consultant.

4/16 - Waiver granted effective 4/15/09.

Bill Text As Introduced

Reprint

Adopted Amend. No.580

**Upcoming Hearings** 

Senate Legislative Operations and

May. 07,

Elections

2009 01:30 PM

<u>Agenda</u>

<u>AB519</u> (BDR1165) – **Elections, Procedures, etc.** - Creates a statutory commission to review continuation of state agencies, boards and commissions and tax exemptions, abatements and earmarked revenue sources.

Most Recent History Action: Apr 09, 2009 - Exemption effective.

AB525 (BDR1224) — Health & Human Services — Greates the Division of Medical Professional Boards of the Department of Health and Human-Services, 4/10 died

<u>SB8</u> (BDR 216) - Legislative Committee on Health Care (NRS 439B.200) - Makes various changes related to the process for appointment to certain medical boards.

Bill Text As Introduced 1st Reprint

Adopted

Amendments Amend. No.418

Assembly Commerce and Labor May. 04, No Action.

SB21 (BDR-260)—Attorney-General—Revises-previsions-governing-the-sale or offer-of-sale of certain food, drugs and other-commodities-after-the-date-of-expiration of the commodity-has-passed-Amend #167, pied 4/22

<u>SB31</u> (BDR 305) - **Purchasing Division-Administration** - Consolidates the provisions governing state procurement of services with the independent contractor provisions and authorizes the State Board of Examiners to delegate administrative approval for certain contracts.

Bill Text As Introduced 1st Reprint

Adopted Amendments Amend. No.32

Assembly Government Affairs Apr. 27, No Action Action

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LEGISLATIVE ADVOCACY **GOVERNMENT RELATIONS** 

SB32-(BDR-459) Nevada-Association of Counties Allows performance evaluations of appointed public efficers and employees to be conducted in a closed meeting unless the officer or employee requests the evaluation be hold in an open-meeting: 4/10 died

SB72 (BDR 3376) - Senator Cegavske - Authorizes a registered pharmacist to perform certain screening tests.

**Bill Text** 

As Introduced 1st Reprint

**Adopted Amendments** 

Amend. No.461

Assembly Commerce and Labor

May. 01, 2009 Upon

No

Adjournment

Action.

SB76 (BDR 263) - Attorney General - Revises provisions governing the administrative procedures for the summary suspension of licenses issued by certain state agencies.

**Bill Text** 

As Introduced

1st Reprint

Adopted Amendments

Amend. No.9

Apr. 28, 2009

09:00

Assembly Government Affairs No Action

SB79 (BDR 327) - Health and Human Services, Department of - Revises provisions governing various commissions, boards and committees relating to health.

**Bill Text** 

As Introduced 1st Reprint

**Adopted Amendments** 

Amend. No.137

May. 06,

No

Assembly Health and Human Services

2009 01:30 PM

Action.

SB159 (BDR 14) - Senator Cegavske & Assemblyman Anderson - Requires the establishment of a Cancer Drug Donation Program.

Bill Text

As Introduced 1st Reprint

Adopted **Amendments** 

Amend. No.95

Assembly Health and Human

Apr. 22,

No

Services

2009 01:30 PM

Action

SB168 (BDR 1011) - Senator Care - Revises provisions relating to prescription drugs.

**Bill Text** 

As Introduced 1st Reprint

**Adopted Amendments** 

Amend. No.217

Assembly Commerce and

May. 01, 2009 Upon

Labor

Adjournment

No Action.

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LEGISLATIVE ADVOCACY **GOVERNMENT RELATIONS** 

SB197 (BDR804) - Senator Wiener & 12 others - Revises provisions relating to the re-issuance of certain prescription drugs.

**Bill Text** 

As Introduced

1st Reprint

**Adopted Amendments** 

Amend, No.94

Assembly Commerce and

May. 01, 2009 Upon

No

Labor

Adjournment

Action

SB211 (BDR1056) - Enacts provisions relating to manufacturers and wholesalers of prescription drugs. 4/10 died

SB267 (BDR62) - Wiener - Makes various changes concerning the procedures for adopting administrative regulations and the requirements of the Open Meeting Law.

Assembly Government Affairs

May. 04, 2009 09:30 AM

No Action.

SB268 (BDR161) - Carlton - Makes various changes to provisions governing occupational licensing boards...

Bill Text As Introduced

1st Reprint Amend. No.421

Assembly Commerce and Labor

May. 04, 2009 01:30 PM

No Action.

SB271-(BDR876)—Schneider—Provides for the practice of alternative medicine in this State. 4/10

SB279 (BDR82) - Care - Makes various changes relating to public records. 4/10 died

SB284 (BDR687) - Townsend - Exempts certain retired public officers and employees from disqualification for retirement allowances for reemployment with a public employer under the Public Employees' Retirement System.

4/6 - Notice of exemption.

SB296-(BDR671) - Washington -- Enacts-provisions-relating-to-complementary-and-alternative health-care-practices. 4/10 died

SB305 (BDR845) - Parks & 9 others - Makes various changes concerning a prescription for the sexual partner of a person diagnosed with a sexually transmitted disease.

**Bill Text** 

As Introduced

1st Reprint

**Adopted Amendments** 

Amend. No.171

Assembly Health and Human

May. 04, 2009

01:30 No

Services

Action.

SB362 (BDR217) - Commerce & Labor - Clarifies and revises provisions related to the suspension or revocation of professional licenses by health care professional licensing boards. Assembly Commerce and Labor May, 04, 2009 01:30 PM No Action.

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LEGISLATIVE ADVOCACY GOVERNMENT RELATIONS

<u>SB364</u> (BDR220) – **Commerce and Labor** - Revises provisions relating to professional licensing boards and professional licenses.

**Bill Text** 

As Introduced 1st Reprint

**Adopted Amendments** 

Amend. No.425

Assembly Commerce and

May. 06,

No

Labor

2009 01:30 PM

Action.

SB367 (BDR1168) – Finance - Makes various changes to the provisions governing the Public Employees' Retirement System.

4/6 – Notice of exemption.



# National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014 Tel: 847/391-4406 • Fax: 847/391-4502 Web Site: www.nabp.net

TO:

**EXECUTIVE OFFICERS - STATE BOARDS OF PHARMACY** 

FROM:

Carmen A. Catizone, Executive Director/Secretary

DATE:

April 16, 2009

RE:

DEA Interpretation of the Emergency Schedule II Refill Rule – Overnight

Shipping Precludes use of Rule in Hospice Settings

In reference to the dispensing of Schedule II controlled substances in emergency situations pursuant to an oral prescription<sup>i</sup>, attached you will find a letter recently issued by the United States Drug Enforcement Administration (DEA) that states "a hospice that chooses to establish a routine practice of having its patients' controlled substances prescriptions filled exclusively by a pharmacy that ships the controlled substances via overnight delivery – rather than arranging for the controlled substances to be delivered the same day the prescription is issued so that the medication can be immediately administered to the patient – may not avail itself of the emergency oral prescription allowance for Schedule II controlled substances, which must be limited to true emergencies."

In the attached letter, DEA notes that a hospice pharmacy may rely on 21 CFR 1306.11(g), which allows a prescription written for a Schedule II narcotic substance for a hospice patient to be transmitted by the prescriber or agent to the pharmacy by facsimile and such facsimile serves as the original written prescription.

NABP has been informed that this position is being enforced and is advising state boards that other pharmacies may be engaged in such activities and subject to action by the DEA.

NABP has not taken an official position on this issue, but will be reviewing it in the context of its mission to protect public health.

Feel free to contact Melissa Madigan at mmadigan@nabp.net if you have any questions.

<sup>i</sup> 21 USC 829(a) allows, in emergency situations, the dispensing of a Schedule II controlled substance upon an oral prescription. 21 CFR 1306.11(d) outlines the requirements for such dispensing:

- The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);
- The prescription shall be immediately reduced to writing by the pharmacist and shall contain all
  information required in Sec. 1306.05, except for the signature of the prescribing individual practitioner;
- If the prescribing individual practitioner is not known to the pharmacist, he must take a reasonable effort to
  determine that the oral authorization came from a registered individual practitioner, which may include a
  callback to the prescribing individual practitioner using his phone number as listed in the telephone
  directory and/or other good faith efforts to insure his identity; and
- Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall
  cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing
  pharmacist. In addition to conforming to the requirements of Sec. 1306.05, the prescription shall have
  written on its face "Authorization for Emergency Dispensing."

21 CFR 290.10 defines "emergency situation" for the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II as a situation in which the prescribing practitioner determines:

- That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and
- That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act, and
- That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be
  presented to the person dispensing the substance, prior to the dispensing.



# U. S. Department of Justice Drug Enforcement Administration

www.dea.gov

Springfield, Virginia 22152

NOV 1 4 2008

The Honorable Louie Gohmert United States House of Representatives Washington, D.C. 20515

Dear Congressman Gohmert:

Thank you for your letter to the Drug Enforcement Administration (DEA) dated October 6, 2008, regarding the dispensing of schedule II controlled substances in emergency situations pursuant to an oral prescription. As a preliminary matter, please be advised that the allowance of oral prescribing for this purpose is not merely DEA policy but an express statutory provision. Specifically, as set forth in the Controlled Substances Act, "in emergency situations, as prescribed by the Secretary [of Health and Human Services] by regulation after consultation with the Attorney General, [a schedule II controlled substance] may be dispensed upon oral prescription in accordance with section 503(b) of [the Federal Food, Drug, and Cosmetic Act]." 21 U.S.C. § 829(a). The DEA regulations provide likewise and, as you indicate, require, among other things, that the prescribing practitioner deliver to the dispensing pharmacist, within seven days of the oral prescription, a written prescription for the emergency quantity prescribed. 21 C.F.R. § 1306.11(d).

You specifically ask whether pharmacies that dispense controlled substances to hospice patients may use overnight shipping to deliver schedule II controlled substances on an emergency basis pursuant to an oral prescription. To address this question, one must first consider the definition of an "emergency" under which a schedule II controlled substance may be dispensed pursuant to an oral prescription. As set forth in 21 C.F.R. § 290.10:

For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the federal Controlled Substances Act, the term emergency situation means those situations in which the prescribing practitioner determines:

- (a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and
- (b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, and
- (c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

The Honorable Louie Gohmert

Page 2

As this regulation indicates, the allowance for oral prescribing of a schedule II controlled substance in emergency situations contemplates that that the controlled substance will be immediately administered. In contrast, in the scenario about which you inquire, the pharmacy does not deliver the controlled substance to the patient until the day after the practitioner writes the prescription, thereby preventing the immediate administration of the controlled substance to the patient. Such lack of immediate administration is inconsistent with the foregoing definition of "emergency situation" set forth in 21 C.F.R. § 290.10. Accordingly, a hospice that chooses to establish a routine practice of having its patients' controlled substances prescriptions filled exclusively by a pharmacy that ships the controlled substances via overnight delivery – rather than arranging for the controlled substances to be delivered the same day the prescription is issued so that the medication can be immediately administered to the patient – may not avail itself of the emergency oral prescription allowance for schedule II controlled substances, which must be limited to true emergencies.

Nonetheless, a hospice that elects to conduct business in this manner (by relying exclusively on a pharmacy that delivers drugs solely by overnight delivery) may expedite the process by relying on another provision of the DEA regulations that is specifically geared toward hospice settings. As set forth in 21 C.F.R. § 1306.11(g) (emphasis added):

A prescription prepared in accordance with 21 C.F.R. § 1306.05, written for a schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with 21 C.F.R. § 1304.04(h).

Thus, where the patient is in such a hospice setting and schedule II narcotic medication is needed, a faxed prescription of a practitioner may be filled by pharmacy — without the requirement of an emergency. This special allowance in the regulations was promulgated by DEA for the very purpose of accommodating patients in the hospice setting by allowing an additional optional method (one not generally available in other settings) to facilitate the dispensing of schedule II narcotics to patients.

Thank you for your interest in this matter. If you should have any further questions, please do not hesitate to contact me again.

Eric J. Akers, Section Chief

Congressional Affairs Section

# **FYI: New Rules Implement Ryan Haight Act**

Wanda C. Cox

Sent: Thursday, April 16, 2009 2:37 PM

To: LARRY L. PINSON

### New Rules Implement Ryan Haight Act

Apr 15, 2009, By Corey McKenna



Photo: Ryan Haight died at 18 of a drug overdose in 2001 after he procured Vicodin over

the Internet.

New Drug Enforcement Administration (DEA) regulations implementing the Ryan Haight Act went into effect on April 13th. The Interim Final Rule was published in the Federal Register this week, and the public has 60 days from its publication to submit comments to the DEA.

The Ryan Haight Act was named for an 18-year-old who died after overdosing on a prescription painkiller he obtained on the Internet from a medical doctor he never saw. After his death, Haight's story became a rallying point for relatives of others who had died from prescription drug overdoses to encourage the passage of the legislation that bears his name.

Like Haight, nearly one in five teenagers has used a prescription medication to get high, according to the 2008 Partnership Attitude Tracking Survey (PATS) conducted by the Partnership for a Drug-Free America. The same survey found that two in five teens believe the fallacy that prescription medicines obtained without a prescription are "much safer" to use than illegal drugs. The 2008 Monitoring the Future survey sponsored by the National Institute on Drug Abuse found that 7 of the top 10 drugs abused by high school seniors are prescription or over-the-counter medications. Prescription drugs are now as common as marijuana as the gateway to recreational drug use and abuse by teenagers.

Unscrupulous or "rogue" Internet pharmacies exist to profit from the sale of controlled prescription medicines to buyers who have not seen a doctor and don't have a prescription from a registered physician. The pharmacies lack quality assurance and accountability, and their products pose a danger to buyers. They pretend to be authentic by operating websites that advertise powerful drugs with the "approval" of a "doctor" working for the drug trafficking network. Prescription medications are powerful drugs that, while lifesaving under some circumstances, can be harmful or even lethal under others, and registered physicians and pharmacists exist to advise consumers on the difference. DEA maintains a hotline for reporting suspicious Internet pharmacies.

"Now that this law has been put into force it will be harder for cyber-criminals to supply controlled substances over the Internet and easier for us to prosecute them," said DEA Acting Administrator Michele M. Leonhart. "These regulations add important new provisions to prevent the illegal distribution of controlled substances through the Internet. Its implementation will increase Internet safety and help prevent tragedies like Ryan Haight's death from happening again."

The statute amends the Controlled Substances Act (CSA) by adding several new provisions to prevent the illegal distribution of controlled substances by means of the Internet. The rules would require at least one face-to-face medical evaluation before a patient could receive a prescription for a controlled substance over the Internet.

The new rules also place tougher restrictions on online pharmacies. The rules create new definitions of what classifies as an

online pharmacy and what it means to deliver, distribute or dispense meds by means of the Internet.

Rather than try to block all online pharmaceutical sales, the rules called for by the Ryan Haight Act put online pharmaceutical sales on an equal regulatory footing with sales made through a brick-and-mortar facility. The rules require an endorsement of an existing registration to allow existing pharmacies to sell controlled substances online. This means law enforcement will be able to carefully scrutinize all applications for such registration and be able to easily separate legitimate and illegitimate Internet operations. The rules also set prescription reporting requirements for online pharmacies.

Consistent with the CSA itself, the Ryan Haight Act relates solely to controlled substances. Controlled substances are those psychoactive drugs and other substances - including narcotics, stimulants, depressants, hallucinogens, and anabolic steroids -- that are placed in one of the five schedules of the CSA due to their potential for abuse and likelihood that they may cause psychological or physical dependence when abused. Controlled substances constitute only a small percentage of all pharmaceutical drugs. Approximately 10 percent of all drug prescriptions written in the United States are for controlled substances, with the remaining approximately 90 percent of prescriptions being written for non-controlled substances. The amendments to the CSA made by the Ryan Haight Act, as well as the regulations being issued here, do not apply to non-controlled substances.

CAM

#### You May Also Like

- Ryan Haight Act will Require Tighter Restrictions on Internet Pharmacies
- GlaxoSmithKline Cuts Supplies to Internet Pharmacies Selling to U.S.
- Internet Pharmacies Draw Scrutiny
- Online Pharmacies Fined

### Virginia: Hackers Demand \$10 Million for Stolen State Data

### Alisanne Maffei

Sent:

Friday, May 08, 2009 11:08 AM

To:

LARRY L. PINSON; Jeri Walter; Carolyn J. Cramer

Cc:

Christopher Ipsen; NSavage@ag.nv.gov

Importance: High

UPDATE ON OTHER STATE TECHNOLOGY TRENDS

# **Hackers Want Millions For Data on Prescriptions**

### Theft of Va. Patient Records Claimed

By Brian Krebs and Anita Kumar; Washington Post Staff Writers; Friday, May 8, 2009

RICHMOND, May 7 -- The FBI and Virginia State Police are searching for hackers who demanded that the state pay them a \$10 million ransom by Thursday for the return of millions of personal pharmaceutical records they say they stole from the state's prescription drug database.

The hackers claim to have accessed 8 million patient records and 35 million prescriptions collected by the Prescription Monitoring Program.

"This was an intentional criminal act against the commonwealth by somebody who was trying to harm others," Gov. Timothy M. Kaine (D) said. "There are breaches that happen by accident or glitches that you try to work out. It's difficult to foil every criminal that may want to do something against you."

Although the hackers had threatened to sell the data if they did not receive payment by Thursday, the deadline passed with no immediate sign that they followed through.

State officials say it is unclear whether the hackers were able to view the patient records, as they have claimed. If the theft is real, it would be the most serious cybercrime the state has faced in recent history...

State officials learned April 30 that hackers had replaced the site's home page with a ransom note demanding the payment in exchange for a password needed to retrieve the records, according to a posting on Wikileaks.org, an online clearinghouse for leaked documents.

"For \$10 million, I will gladly send along the password," the ransom note read. "You have 7 days to decide. If by the end of 7 days, you decide not to pony up, I'll go ahead and put this baby out on the market and accept the highest bid."

The program's computer system has been shut down since last week's breach, but all data were backed up and those files have been secured, Whitley Ryals said. Virginians are still able to get prescriptions filled.

"We do have some of the systems restored, but we're being very careful in working with experts and authorities to take essential steps as we proceed forward," she said.

The state-run database helps doctors and pharmacies track powerful narcotics and painkillers to reduce the abuse, theft and illegal sale of the controlled substances sold under labels including OxyContin and Vicodin. It was set up as a pilot program in southwestern Virginia in 2003 and went statewide in 2006. About 2,500 health-care professionals have access to the data.

Emily Wingfield, chief deputy director of the Department of Health Professions, said the database contained 31.3 million prescription records as of Jan. 1. About 1 million records are added every month, she said.

State officials say they have no evidence that any personal information is at risk, but they recommend that anyone concerned about possible identity theft keep track of personal financial statements and periodically review credit reports.

http://www.washingtonpost.com/wp-dyn/content/article/2009/05/07/AR2009050702515.html

**News Release**: <u>Statement by DHP Director Sandra Ryals on Potential Breach of Security for Prescription Monitoring Program</u> - May 6, 2009

More Information: Questions and Answers about the Department and the PMP program - May 6, 2009

### Virginia: Hacked State Database Slowly Being Restored - update

#### Alisanne Maffei

Sent: Tuesday, May 12, 2009 12:28 PM

To: Christopher Ipsen; jearl@ag.nv.gov; Pharmacy Board; LARRY L. PINSON; Jeri Walter; Carolyn J. Cramer

Cc: NSavage@ag.nv.gov; Linda DeSantis; Chris W. Finnegan; Donna Crutcher; Frank B. Briggs; Jenet Hensley; John Lusak;

Shirlee Bingham

Update on other state technology security issues:

# State drug database regaining functions after cyberattack

Norfolk Virginian-Pilot

The Virginia Department of Health Professions is slowly restoring its computer functions in the wake of a hacker attack but still can't say whether the hacker got access to millions of Virginians' prescription drug records.

A criminal investigation of the April 30 cyberattack on the state Prescription Monitoring Program is still under way, department spokeswoman Kathy Siddall said Monday.

In an unauthorized message on the department's Web site, the hacker claimed to have gained access to more than 35 million prescription records in a database designed to deter prescription drug abuse and demanded a \$10 million ransom, according to the open-government Web site Wikileaks. The investigation has not yet confirmed whether the hacker's claim is true, Siddall said.

The department's entire computer operation was shut down as a result of the breach. E-mail has now been restored, but most other functions are still offline, Siddall said.

The department's highest priority is restoring its computerized licensing functions for the thousands of doctors, nurses, pharmacists and other health care workers it regulates, she said. Those functions are now being handled in person or by phone or mail.

The prescription drug database "won't be brought back up until it's completely secure," she added.

The database contains prescriptions for certain federally controlled drugs with a high potential for abuse, such as OxyContin, Vicodin and Xanax. The records include patients' name, address and date of birth, the name and quantity of the drug prescribed, and identifying numbers for the doctor and pharmacist.

In a few cases, pharmacists may have used customers' Social Security numbers as identifiers in entering the data, Siddall said. State officials said it's unlikely that identity theft could occur as a result of the breach. They are nevertheless advising Virginians to check their bank accounts and credit reports for signs of trouble.

If it is determined that anyone's personal information was compromised, they will be notified, Gov. Timothy M. Kaine said Monday.

"There was a lot of security on this database," Kaine said. "It was not easy to get into. It was a very sophisticated effort to do it. But that means we've got to create more sophisticated security, and we take that very seriously."

Pilot writer Julian Walker contributed to this report. Bill Sizemore, (757) 446-2276, bill.sizemore@pilotonline.com

http://hamptonroads.com/2009/05/state-drug-database-regaining-functions-after-cyberattack

An update provided by State of Nevada DolT Research, please advise if you are interested in any additional details or materials, thanks:

Alisanne Maffei

Nevada Department of Information Technology Research <a href="mailto:awmaffei@doit.nv.gov">awmaffei@doit.nv.gov</a>

To provide research on current and emerging areas of technology and other states trends to ensure efficient and cost effective deployment of government services, reduce the risks of innovation through IT analysis, and disseminate relevant information via various outlets.

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### **RE: Pharmacy Tech Programs**

David J. Perlman

Sent: Friday, April 17, 2009 2:31 PM

To: LARRY L. PINSON

#### I can mandate that and will.

David Perlman, Administrator
Nevada Commission on Postsecondary Education
3663 East Sunset Road Suite 202
Las Vegas, NV 89120
702-486-7330 ph
702-486-7340 fx
dperlman@cpe.state.nv.us
www.cpe.state.nv.us

From: LARRY L. PINSON

**Sent:** Friday, April 17, 2009 12:11 PM

**To:** David J. Perlman **Cc:** Carolyn J. Cramer

Subject: Pharmacy Tech Programs

### Good morning David:

You were kind enough a couple years ago to help me tighten up a questionable pharmacy tech program and once again I ask for your insight. Pharmacy Technician programs exist around the state, and are generally quite expensive for the student (between \$10K and \$14K for a 6 mo. course). A pharmacy technician must be registered by the Board of Pharmacy prior to beginning work in a pharmacy, and as you might imagine, the registration process involves criminal background checks including drug use and abuse, as well as random drug testing by most employing pharmacies.

Generally, students are well into or have completed the program (and have spent all of that money) when they make application to us, only to find that past activities revealed on that application might prevent them from getting licensed and require them to appear before the Board for approval, which may not be forthcoming.

Our concern is that these students are not being forewarned by the schools of the above, and it really bothers both Board staff and the Board itself, that some of these kids spend so much, then test positive for some illicit drug or have a criminal background that would prevent them from getting licensed, and their career is over.

We are not certain about how to best approach the above, so would appreciate your advice!

Thank you,

Larry L. Pinson, Pharm. D.

**Executive Secretary** 

Nevada State Board of Pharmacy

### **RE: Pharmacy Tech Programs**

David J. Perlman

Sent: Friday, April 17, 2009 4:14 PM

To: LARRY L. PINSON

Okay - I am notifying all the schools that offer phar tech to include PRIOR to registration.

David Perlman, Administrator
Nevada Commission on Postsecondary Education
3663 East Sunset Road Suite 202
Las Vegas, NV 89120
702-486-7330 ph
702-486-7340 fx
dperlman@cpe.state.nv.us
www.cpe.state.nv.us

From: LARRY L. PINSON

Sent: Friday, April 17, 2009 4:11 PM

To: David J. Perlman

Subject: RE: Pharmacy Tech Programs

Makes sense. Previous criminal history does not always lead to registration denial, however they at least need to know that it is a risk, as is testing positive for controlled substances.

Larry

Larry L. Pinson, Pharm. D. Executive Secretary Nevada State Board of Pharmacy (775) 850-1440 (775) 850-1444 (fax)

From: David J. Perlman

Sent: Friday, April 17, 2009 4:08 PM

To: LARRY L. PINSON

Subject: RE: Pharmacy Tech Programs

No problem. Would like them to screen via the background process or simply make the student sign a statement that he knows of the requirement and has not been so convicted?

David Perlman, Administrator
Nevada Commission on Postsecondary Education
3663 East Sunset Road Suite 202
Las Vegas, NV 89120
702-486-7330 ph
702-486-7340 fx
dperlman@cpe.state.nv.us
www.cpe.state.nv.us

From: LARRY L. PINSON

Sent: Friday, April 17, 2009 3:04 PM

To: David J. Perlman

Subject: RE: Pharmacy Tech Programs



# Neuada State Board of Pharmacy

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

### **NEVADA STATE BOARD OF PHARMACY**

### **ACTIVITIES REPORT**

# APRIL 15th, 2009 BOARD MEETING HELD IN LAS VEGAS, NEVADA

This report is prepared and presented to keep interested legislators and others abreast of the activities of the Nevada State Board of Pharmacy. Following is a summary of the April 2009 Board meeting.

### **Licensing Activity:**

- 16 licenses were granted for Out-of-State pharmacies.
- 2 licenses were granted for Out-of-State MDEG companies.
- 13 licenses were granted for Out-of-State wholesalers.
- 3 licenses were granted for Nevada pharmacies (pending inspection).

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- 2 licenses was granted for a Nevada MDEG company.

### **Disciplinary Action:**

- Pharmacist TR was revoked for diversion of controlled substances.
- Pharmacist JA's request for reinstatement was denied secondary to unresolved issues in Utah regarding insurance fraud.
- Pharmaceutical technicians CB and RD were referred to PRN-PRN for evaluation of past drug issues prior to granting tech in training licenses.

## Other Activity:

- Besides the usual business activities of the Board, discussions were held on Telepharmacy and legislative issues.
- A report was given from the PT Committee.

### PROPOSED 2010 BOARD MEETING DATES

January 13 & 14, 2010 March 3 & 4, 2010 April 14 & 15, 2010 June 2 & 3, 2010 July 14 & 15, 2010 September 8 & 9, 2010 October 13 & 14, 2010 December 1 & 2, 2010

Las Vegas Reno Las Vegas Reno Las Vegas Reno Las Vegas Reno

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### ANNUAL MEETINGS

APhA Annual Meeting
NABP Annual Meeting
NABP District 8 Meeting
NACDS Annual Meeting
NACDS Pharmacy & Technology
ASHP Summer Meeting
Mid Year Meeting
NASCSA Annual Meeting

March 12-15, 2010 May 22-25, 2010 September? October? April 24-28, 2010 August 28-Sept 1, 2010 June 6-9, 2010 December 5-9, 2010 October 19-22, 2010

Washington, DC Anaheim, CA ?? Palm Beach, FL San Diego, CA Tampa, FL Anaheim, CA Charleston, SC

#### STATE HOLIDAYS

New Years Day
Martin Luther King's Birthday
President's Birthday
Memorial Day
Independence Day
Labor Day
Nevada Day
Veteran's Day
Thanksgiving
Christmas

January 1, 2010 January 18, 2010 February 15, 2010 May 31, 2010 July 5, 2010 September 6, 2010 October 29, 2010 November 11, 2010 November 25 & 26, 2010 December 24, 2010

### NAC 639.707 COUNSELING OF PATIENTS Workshop Draft June 4, 2009

# NAC 639.707 Counseling of patients: Duties of pharmacist or intern pharmacist; documentation. (NRS 639.070, 639.266)

- 1. Except as otherwise provided in this section, a pharmacist or intern pharmacist under the supervision of a pharmacist shall verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient that:
  - (a) Has not been previously dispensed to the patient from that pharmacy; or
- (b) Has been previously dispensed to the patient from that pharmacy, including, without limitation, a prescription drug or a device that is being refilled, if, in the professional judgment of the pharmacist or intern pharmacist:
  - (1) Such information would further or improve the drug therapy of the patient; or
- (2) A reasonable concern relating to the safety or efficacy of the drug therapy of the patient was raised by the review of the patient's record that the pharmacist or intern pharmacist conducted pursuant to subsection 4.
- 2. The information provided by the pharmacist or intern pharmacist pursuant to subsection 1 must include, without limitation:
  - (a) The name and a description of the drug;
  - (b) The form of dosage, dose, route of administration and duration of drug therapy;
  - (c) The intended use of the drug or device and expected responses from that use;
- (d) Any special directions and precautions for the preparation, administration and use of the drug or device by the patient;
- (e) Any common severe side effects, interactions and contraindications that may occur, recommendations to avoid these side effects, interactions or contraindications, and the action required if they occur;
  - (f) Techniques for the patient or the person caring for the patient to monitor the drug therapy;
  - (g) Proper storage of the drug or device:
  - (h) Information about refilling the prescription;
  - (i) Actions to be taken in the event of a missed dose;
  - (j) Any relevant information contained in the record of medication of the patient; and
- (k) Any other information which, in the professional judgment of the pharmacist or intern pharmacist, is necessary to assure the safe and effective use of the drug or device by the patient.
- 3. The pharmacist or intern pharmacist shall provide the information required pursuant to subsections 1 and 2 in written form to the patient if a drug or device will be distributed to the patient outside the confines of the pharmacy by mail or any other delivery service. A pharmacist or intern pharmacist is not required to provide written information pursuant to this subsection if the drug or device is being delivered to a patient who is in a licensed medical facility where other licensed health care professionals are authorized to administer drugs.
- 4. The pharmacist or intern pharmacist shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness <u>and may consider</u> [by considering]:
  - (a) Overutilization of the drug and drug abuse;
  - (b) Underutilization of the drug and therapeutic ineffectiveness;
  - (c) Therapeutic duplications and contraindications:
  - (d) Interactions between the drug and any:

- (1) Other drugs which the patient is taking or has recently taken;
- (2) Diseases which the patient has, including any stages of that disease; and
- (3) Allergies that the patient may have; [and]
- (e) Incorrect dosage or duration of treatment[-]; and

### (f) Black box warnings.

- 5. A pharmacist or intern pharmacist is not required to counsel a patient pursuant to this section if the patient or a person caring for the patient refuses to accept the counseling.
- 6. Except as otherwise provided in subsection 9, the pharmacist or intern pharmacist shall, at the time that counseling is provided or refused:
- (a) Initial by his own hand a written document that is maintained at the pharmacy to record whether counseling was provided to or refused by a patient or the person caring for the patient; or
- (b) Enter an initial or other identifying mark onto a record in a computerized system used by the pharmacy for recording information concerning prescriptions to indicate whether counseling was provided to or refused by a patient or the person caring for the patient.
- 7. In addition to meeting the requirements set forth in NAC 639.910 to 639.938, inclusive, a computerized system used by a pharmacist or intern pharmacist pursuant to paragraph (b) of subsection 6 must:
- (a) Be capable of indelibly recording the date and time the pharmacist or intern pharmacist entered the initial or other identifying mark onto the record in the computerized system;
- (b) Require the entry of an initial or identifying mark every time a record concerning counseling is created or altered; and
- (c) Prohibit the creation or alteration of a record concerning counseling by a person other than the pharmacist or intern pharmacist who has counseled or attempted to counsel the patient or the person caring for the patient.
- 8. A pharmacy shall retain the documentation described in subsection 6 in the records of the pharmacy for at least 2 years.
- 9. The pharmacist or intern pharmacist is not required to comply with the provisions of subsection 6 if:
  - (a) The prescription drug or device dispensed to the patient is being refilled; and
- (b) The patient or the person caring for the patient refuses to accept counseling from the pharmacist or intern pharmacist.

(Added to NAC by Bd. of Pharmacy, eff. 11-15-93; A 9-6-96; R016-03, 10-21-2003)

## Draft of Fulfillment Regulations from March 26, 2009 Meeting

- 1. A prescription may be filled or refilled by a fulfillment pharmacy for a dispensing pharmacy if:
- (a) The dispensing pharmacy enters the data concerning the prescription into its computer system and transfers that data to the computer system of the fulfillment pharmacy in a secure and confidential manner;
  - (b) The computer system of the dispensing pharmacy:
- (1) [Transmits to the computer system of the fulfillment pharmacy the National Drug Code number of a generic drug in stock that the dispensing pharmacy would have used to fill or refill the prescription if the prescription had not been transmitted to the fulfillment pharmacy] Must transmit the current NDC that is available to the fulfillment pharmacy and if the prescription is not available then the prescription will be transmitted back to the dispensing pharmacy to be filled or refilled;
- (2) Makes and retains a record documenting the date and time that the prescription is transmitted to the fulfillment pharmacy and the identity of the fulfillment pharmacy; and
  - (3) If applicable, automatically reduces the number of refills of the prescription;
- (c) The computer systems of the dispensing pharmacy and the fulfillment pharmacy are operated in compliance with the applicable provisions of this chapter and chapter 639 of NRS;
- (d) The fulfillment pharmacy labels the container in which the prescription will be dispensed in compliance with NRS 639.2801 using a label from the dispensing pharmacy or a label that contains the same information as the dispensing pharmacy would have been required to place on the label if the dispensing pharmacy had filled or refilled the prescription;
- (e) For each prescription that is being filled for the first time [by the fulfillment pharmacy], a pharmacist employed by the dispensing pharmacy shall:
- (1) Verifies the correctness of the data in the computer system of the dispensing pharmacy concerning the prescription before the prescription is transmitted to the fulfillment pharmacy to be filled, if:
- (I) The computer system of the dispensing pharmacy is capable of recording the identification of the pharmacist and the date and time when the pharmacist performed the verification; and
- (II) The pharmacist properly records in the computer system of the dispensing pharmacy his verification of the data or notes the verification directly on the prescription hardcopy; or
- (2) Verifies the correctness of the prescription drug ordered by the prescription when it is received from the fulfillment pharmacy and the pharmacist makes a written notation on the prescription or in the record of the prescription in the computer system of the dispensing pharmacy that includes his name and the date on which he performed the verification; and
- (f) For each prescription that is being refilled by the fulfillment pharmacy, a pharmacist or pharmacy technician employed by the dispensing pharmacy:
- (1) Makes a record, by hand on a written document or in the record of the prescription in the computer system of the dispensing pharmacy, that includes:
- (I) The date that the request to refill the prescription was sent to the fulfillment pharmacy;
- (II) The date that the prescription drug ordered to refill the prescription was received by the dispensing pharmacy from the fulfillment pharmacy; and

- [(III) The date that the prescription drug was dispensed to the patient or an agent of the patient; and]
- (2) Verifies the correctness of the prescription drug ordered to refill the prescription when the prescription drug is received from the fulfillment pharmacy if, in his professional judgment, the pharmacist determines such verification is necessary.
- [2. If a fulfillment pharmacy fills or refills a prescription pursuant to this section with a generic drug that is manufactured by a different manufacturer than the manufacturer used by the dispensing pharmacy, the fulfillment pharmacy shall show on the label of the container in which the prescription will be dispensed the name of the manufacturer of the generic drug used to fill or refill the prescription and the computer system of the fulfillment pharmacy must transmit to the computer system of the dispensing pharmacy the National Drug Code number and the price of that generic drug. If the computer system of the fulfillment pharmacy is incapable of transmitting such data to the dispensing pharmacy, the fulfillment pharmacy shall not fill or refill the prescription and shall notify the dispensing pharmacy that the fulfillment pharmacy cannot fill or refill the prescription.]
  - [3]2. If a dispensing pharmacy:
- (a) Does not include prescription drugs ordered by prescriptions that are filled or refilled by a fulfillment pharmacy in the inventory of the dispensing pharmacy, the dispensing pharmacy shall, not later than 30 days after receipt of a prescription drug ordered by a prescription that was filled or refilled by a fulfillment pharmacy:
- (1) Return the prescription drug to the fulfillment pharmacy that filled or refilled the prescription if the prescription drug has not been dispensed to a patient or an agent of a patient; and
- (2) Ensure that a pharmacist employed by the dispensing pharmacy records the date that the prescription drug was returned to the fulfillment pharmacy on a written document that is maintained at the dispensing pharmacy or in the record of the prescription in the computer system of the dispensing pharmacy.
- (b) Includes prescription drugs ordered by prescriptions that are filled or refilled by a fulfillment pharmacy in the inventory of the dispensing pharmacy, the dispensing pharmacy shall:
- (1) Not take possession of a prescription drug ordered by a prescription that was filled or refilled by a fulfillment pharmacy unless the prescription drug is accompanied by an invoice;
- (2) File and process an invoice for each prescription drug that it receives from a fulfillment pharmacy in the same manner as the dispensing pharmacy files and processes invoices for prescription drugs that it receives from a wholesaler; and
- (3) Process and treat each prescription drug ordered by a prescription that is filled or refilled by a fulfillment pharmacy in the same manner as the dispensing pharmacy processes and treats prescription drugs that originate from the inventory of the dispensing pharmacy.
- [4] 3. The transmission of a prescription by a dispensing pharmacy to a fulfillment pharmacy pursuant to this section is not a transfer of a prescription.
  - [5] 4. A dispensing pharmacy shall ensure that:
- (a) A patient has been counseled in compliance with  $\underline{NRS}$  639.266 and  $\underline{NAC}$  639.707 and 639.708; and
  - (b) All communications with the patient are made by and through the dispensing pharmacy.
- [6]5. If a prescription is transmitted to and filled or refilled by a fulfillment pharmacy pursuant to this section, both the dispensing pharmacy and the fulfillment pharmacy are

individually responsible for ensuring that their portion of the prescription has been filled or refilled correctly.

- [7]6. A dispensing pharmacy shall not transmit, and a fulfillment pharmacy shall not fill or refill, a prescription pursuant to this section for any controlled substance listed in schedule II.
  - [8] 7. As used in this section:
  - (a) "Dispensing pharmacy" means a pharmacy licensed by the Board that:
- (1) Sends a prescription to a fulfillment pharmacy to be filled or refilled by the fulfillment pharmacy; and
- (2) Dispenses the prescription drug ordered by the prescription and filled or refilled by the fulfillment pharmacy to the ultimate user unless the fulfillment pharmacy is a mail order pharmacy.
- (b) "Fulfillment pharmacy" means a pharmacy licensed by the Board that fills or refills prescriptions on behalf of a dispensing pharmacy.
  - (c) "Wholesaler" has the meaning ascribed to it in NRS 639.016.
- [(d) Mail order pharmacy" means a pharmacy licensed by the Board that dispenses the majority of its prescriptions though the mail or common carrier to the ultimate user.]

# **Changes to the MDEG Regulations Regarding Qualifications for Administrators**

(Version 2/23/09)

### NAC 639.694 Administrator required. (NRS 639.070)

- 1. Each medical products provider or medical products wholesaler shall have an administrator at all times. The administrator must be a natural person who is employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week. The administrator shall ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and
  - (a). An applicant for administrator must:
  - (1) Be a high school graduate or the equivalent and have 1,500 hours of verified experience working in the area of the products to be provided by the medical provider or medical products wholesaler; or
  - (2) A two years degree or more in a medical field that is directly related to patient health care.
- 2. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after such cessation. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after such employment.
- 3. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.
  - 4. The change of administrator must be approved by the Board.

(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001)

# Draft of NAC 639.725 Use of Mechanical Counting Devise for Dispensing Medication to Be Taken Orally- Discussion and Deliberation June 3, 2009

# NAC 639.725 Use of mechanical counting device for dispensing medication to be taken orally. (NRS 639.070, 639.2655, 639.2801)

- 1. A mechanical counting device that is used by a pharmacy for dispensing medication to be taken orally must use one of the following methods to identify the contents of the device:
  - (a) The following information must be affixed to the front of each cell of the device:
    - (1) The generic name or trade name of the medication;
    - (2) The manufacturer of the medication;
    - (3) The strength of the medication;
    - (4) The expiration date of the medication;
    - (5) The lot number of the medication; and
    - (6) The initials of the pharmacist who:
      - (I) Placed the medication into the device; or
- (II) Verified the correctness of the drug placed into the device when the drug was placed by a pharmaceutical technician, a pharmaceutical technician in training or an intern pharmacist; or
- (b) A label that shows the generic name or trade name, the manufacturer's expiration date and the strength of the medication must be affixed to each cell of the device and a log must be kept for each cell which contains:
  - (1) An identification of the cell by the name of the medication or the number of the cell;
  - (2) The name of the manufacturer of the medication;
  - (3) The expiration date of the medication;
  - (4) The lot number of the medication;
  - (4) (5) The amount of the medication placed in the device; and
  - (5) (6) The initials of the pharmacist who:
    - (I) Placed the medication into the device; or
- (II) Verified the correctness of the drug placed into the device when the drug was placed by a pharmaceutical technician, a pharmaceutical technician in training or an intern pharmacist.
- 2. The Board may prohibit a pharmacy from using a mechanical counting device for dispensing medication to be taken orally if the pharmacy does not identify the contents of the device in accordance with the provisions of subsection 1.

(Added to NAC by Bd. of Pharmacy, eff. 3-17-92; A by R039-06, 5-4-2006)

# Workshop Draft of Amendment to NAC 639.528 June 4, 2009

NAC 639.528 Preparation and storage of food in prescription department of pharmacy. (NRS 639.070) Food for consumption by the public must not be:

- 1. Prepared in the prescription department of a pharmacy; or
- 2. Stored in the refrigerator of the prescription department of a pharmacy.
- A pharmacist or a member of the staff of a pharmacy may prepare food in the prescription department of the pharmacy [or store food in the refrigerator of the prescription department of the pharmacy if the food is for his own personal consumption]. Food or drink may not be stored in a refrigerator that is used for medication storage.

4

#### **BOARD MEETING**

at the

Airport Plaza Hotel 1981 Terminal Way Reno

Wednesday, June 3, 2009

Thursday, June 4, 2009

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

### **Board Members Present:**

Keith Macdonald Leo Basch David Chan Donald Fey Chad Luebke Kam Gandhi Mary Lau

### Board Members Absent:

Keith Macdonald absent on June 4, 2009

### **Board Staff Present:**

Larry Pinson Jeri Walter Carolyn Cramer Keith Marcher

### CONSENT AGENDA

- 1. Approval of April 15, 2009, Minutes
- 2. Applications for Out-of-State MDEG Non Appearance:
  - A. American Diabetes Wholesale, LLC Pompano Beach, FL
  - B. Atos Medical, Inc. West Allis, WI
  - C. Avnet, Inc. Chandler, AZ
  - D. Destiny Medical Supply, Inc. Aurora, CO
  - E. Diabetes Care Club, LLC Brentwood, TN
  - F. Kolob Oxygen + Medical Equipment St. George, UT
  - G. Optigen Inc. Jacksonville Beach, FL

- H. Total eMedical, Inc. Pompano Beach, FL
- I. Walgreen Medical Supply, LLC Tinley Park, IL
- J, Wilmington Medical Supply, Inc. Wilmington, NC

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

- K. Apothecary Shop of Scottsdale Scottsdale, AZ
- L. Apothecary Shop of Tucson Tucson, AZ
- M. Axelacare Health Solutions LLC Lenexa, KS
- N. Benecard Central Fill Mechanicsburg, PA
- O. Mayo Clinic Pharmacy Rochester, MN
- P. Meds for Vets Sandy, UT
- Q. San Ysidoro Pharmacy Santa Barbara, CA
- R. Specialty Compounding, LLC Cedar Park, TX

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

- S. Abbott Laboratories, Inc. Fontana, CA
- T. Ace Surgical Supply Co., Inc. Brockton, MA
- U. Bryant Ranch Prepack North Hollywood, CA
- V. Cardinal Health St Charles, MO
- W. DSC Logistics, Inc. Roanoke, TX
- X. Sanvita, Inc. Tampa, FL
- Y. Septodont, Inc. New Castle, DE

### Application for Nevada MDEG – Non Appearance:

Z. Airgas, Northern California & Nevada – Winnemucca, NV

Applications for Nevada Pharmacy – Non Appearance:

- AA. Center for Surgical Intervention, LLC Las Vegas
- BB. Solutions II LTC Henderson
- CC. Target Pharmacy T-2569 Las Vegas

### Discussion:

The consent agenda applications and supporting documents were reviewed.

NOTE: Leo Basch recused from participation in the vote on item 2 I as he is employed by Walgreens. Mary Lau recused from participation in the vote on items 2 I and CC as Walgreens and Target are members of RAN.

### **Board Action:**

Motion: Leo Basch found the consent agenda application information and minutes

to be accurate and complete and moved for approval with the exception of

items I and CC.

Second: Kam Gandhi

Action: Passed Unanimously.

Motion: Chad Luebke moved to approve items 2 I and CC.

Second: David Chan

Action: Passed Unanimously.

### REGULAR AGENDA

3. Applications for Out-of-State Pharmacy – Appearance

A. College Pharmacy – Colorado Springs, CO

Jerry Gillick appeared and was sworn by President Fey prior to answering questions or offering testimony.

Carolyn Cramer prefaced Mr. Gillick's testimony by reviewing the documents he provided and asked why he was appearing when he still had two more violations that had not be cleared up with his Board Order in Colorado. Mr. Gillick explained that other states have licensed College Pharmacy and have paralleled the seven year federal probation. He indicated that he had fixed all of the problems in the pharmacy and feels that this was a good time to get licensed in Nevada. He also stated that he had been with College Pharmacy since May, 2005, and the federal investigation was already in process against the previous owner, Tom Bader. Tom Bader is no longer associated with College Pharmacy in any manner, they do not compound HGH any longer and they do not intend to in the future.

The Board asked Mr. Gillick why he had not checked that College Pharmacy is a retail pharmacy and they will be shipping parenteral products into Nevada on his application. Mr. Gillick indicated that it was an oversight.

### Board Action:

Motion: Leo Basch moved to approve the application for out-of-state pharmacy for

College Pharmacy.

Second: Kam Gandhi

Action: Passed With One Negative vote

B. Med Shop Total Care – Longview, TX

Dee Downing appeared and was sworn by President Fey prior to answering questions or offering testimony.

Ms. Downing indicated that she was the pharmacist in charge for Med Shop Total Care. They are going to work with a surgery center in Nevada to provide a three day post-op pain product to the surgery center for patient specific orders. They have worked out the specifics with the facility and the consulting pharmacist. They are 797 and 795 compliant and have two clean rooms. Ms. Downing advised that Med Shop Total Care is a family owned pharmacy. Her father and sister are both pharmacists in this practice and she has another sister just graduating from pharmacy school and she may also be working at Med Shop Total Care.

### **Board Action:**

Motion: Kam Gandhi moved to approve the application for Med Shop Total Care.

Second: Chad Luebke

Action: Passed Unanimously

4. Disciplinary Action

A. Walgreens #05295 (08-076-PH-N)

Mary Lau recused from participation in this matter as Walgreens is a member of RAN. Leo Basch recused from participation in this matter as he is employed by Walgreens. Kam Gandhi recused from participation in this matter as he has a working relationship with Debra Dorigatti.

Rob Graham was present to represent Walgreens.

Debra Dorigatti, pharmacist for Walgreens, Angela Ortiz, complainant, and Joe Depczynski, Board investigator, appeared and were sworn by President Fey prior to answering questions or offering testimony.

Carolyn Cramer presented 21 exhibits that were accepted into the record. Rob Graham presented one exhibit, Audit/Board of Pharmacy Inspection Report, that was marked Exhibit A and accepted into the record.

Carolyn Cramer called Angela Ortiz to testify. Ms. Ortiz explained that her father, Enrique Ortiz, had amputated his finger in a work related accident. Mr. Ortiz was taken to Concentra Medical Center where he was treated by Dr. Mikel Meyer. Dr. Meyer dressed the wound and provided Mr. Ortiz with a bottle of cephalexin 500 mg. tablets and a prescription for Vicodin. Dr. Meyer also referred Mr. Ortiz to a hand surgeon. The hand surgeon was not immediately available so Mr. Ortiz went to Renown Medical Center where he was seen by Dr. S. Shepherd. Dr. Shepherd wrote additional prescriptions for Vicodin and Keflex. The following day Ms. Ortiz took her father's prescriptions to her work, Sparks Pediatrics, where she copied the prescriptions written by Dr. Shepherd and the prescription for Vicodin from Concentra onto one piece of paper, and faxed the prescriptions to Walgreens #05295. Ms. Ortiz explained that she asked her brother to pick up the prescriptions for her father, however Walgreens

#05295 would not give them to her brother. Ms. Ortiz and her mother went to Walgreens #05295 later that day with Mr. Ortiz's identification so they would release the medication since this was a worker's comp claim. Ms. Ortiz testified that she and Ms. Dorigatti had a heated argument because Ms. Dorigatti would not dispense the Keflex prescription. Ms. Ortiz advised that she was very concerned about her father getting an infection and could not understand why Ms. Dorigatti would not release the medication to her. Ms. Dorigatti gave Ms. Ortiz the filled prescription for Vicodin and she left the store. Ms. Ortiz was questioned regarding counseling and Ms. Ortiz was adamant that she was not counseled upon receiving the Vicodin. Ms. Cramer asked if she ever received the Keflex from Walgreens #05295 and Ms. Ortiz stated that she never went back to Walgreens #05295 nor had any of her family members.

Mr. Graham cross examined Ms. Ortiz, specifically, regarding her testimony on not being counseled by Ms. Dorigatti.

Ms. Cramer had redirect.

Carlos Marquez, an audience member that speaks Spanish, appeared and was sworn by President Fey prior to interpreting Mr. Ortiz's testimony.

Carolyn Cramer and Rob Graham asked Mr. Ortiz questions, through Mr. Marquez, regarding picking up his medications at Walgreens #05295. David Chan asked if Mr. Ortiz still had the empty prescription vials and he indicated that he no longer had them.

Ms. Cramer called Joe Depczynski to testify. Ms. Cramer led Mr. Depczynski through the 21 staff exhibits and he described what each represented. He testified to the specifics he learned from his investigation regarding the Walgreens computer. Mr. Depczynski interviewed Carla Knight, the managing pharmacist for Walgreens #05295, who helped him understand the filling process of Mr. Ortiz's prescriptions. He indicated he used a paper trail to determine who was responsible for the filling and verifying of these prescriptions.

There was discussion about the date in the Walgreens computer that indicated someone was counseled for the Keflex that had not been dispensed to Mr. Ortiz or any member of his family. The date was earlier, actually the fill date, than the prescription was dispensed.

Mr. Graham cross examined Mr. Depczynski and seemed to discount Mr. Depczynski's investigation procedures because he asked Ms. Ortiz if she had been counseled. Mr. Depczynski explained that was part of what he tries to determine when he is doing an investigation. Mr. Graham noted that if Mr. Depczynski was unable to locate records all he had to do was ask because the records are always available either in the store or on a national level. Mr. Graham produced a copy of the Audit/Board of Pharmacy Inspection Report and indicated that all of the information was on this report. Mr. Depczynski stated that he had never seen that report and was unaware that it existed.

The Board questioned Mr. Depczynski and discussed the case at length. After a break, Carolyn Cramer and Rob Graham presented a stipulated agreement to the Board.

Carolyn Cramer recommended dismissing this matter, however in future investigations she would expect that the Audit/Board of Pharmacy Inspection Report and the CAPS reports be given to the Board's staff.

### **Board Action:**

Motion: Chad Luebke moved to dismiss this matter with the agreement Ms.

Cramer suggested.

Second: Kam Gandhi

Action: Passed Unanimously

B. Smith's Pharmacy #392 (08-070-PH-N)

NOTE: Mary Lau recused from participation in this matter as Smith's is a member of RAN.

Carolyn Cramer presented the details of this matter noting it was an instance of a patient receiving a prescription for buproprion SR 150 mg. tablets that belonged to someone else. The stipulated agreement was for a \$500.00 fine and a \$295.00 administrative fee.

### **Board Action:**

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

Second: Chad Luebke

Action: Passed With One Negative Vote

5. Requests for Reinstatement – Appearance:

Henry A. Miller (08-006-RPH-S)

NOTE: Chad Luebke recused from participation in this matter as Mr. Miller was employed by CVS, Mr. Luebke's employer.

Henry Miller and Larry Espadero appeared and were sworn by President Fey prior to answering questions or offering testimony.

Carolyn Cramer advised the Board that Mr. Miller was present to request reinstatement of his pharmacist license. She noted that the terms of Mr. Miller's previous Board Order required him to pay restitution to Smith's and One Point. Mr. Miller indicated that he had paid restitution to both parties to their satisfaction and copies of the letters from Smith's and One Point should be in the Board's files, which they were. Ms. Cramer also noted that Mr. Miller was not to request reinstatement of his license until after June 5<sup>th</sup>,

2009. Since it is the day before the 5<sup>th</sup>, the Board determined they would hear Mr. Miller at this time.

Mr. Miller stated that he joined PRN-PRN and has learned how to deal with his problems and others because he has a support system now. He is in recovery, has been clean and sober for over a year, and has learned how to make better decisions in his life. He indicated that rather than using controlled substances for the pain in his knee from a college football injury, he now seeks help from physical therapy and takes Advil.

Mr. Espadero testified that Mr. Miller is an entirely different person than he was a year ago when he first appeared before the Board. His biggest attribute is that he has learned humility. Mr. Espadero is very happy with Mr. Miller's progress and recommends that he be allowed to practice pharmacy at this time.

The Board questioned Mr. Miller and he showed genuine humility and shared some of his experiences. When asked what he had been doing for a living, he indicated that he was a chauffeur. This experience has made him realize how much he took his pharmacist profession for granted and now he knows that he has to earn the respect of his peers back again. Mr. Miller was asked if he had sought employment as a pharmacist yet and if he had any leads. Mr. Miller stated that he had not looked until he learned the outcome of today's appearance. Mr. Miller also noted that he has kept up with his continuing education.

### Board Action:

Motion: Keith Macdonald moved to lift the suspension of Mr. Miller's pharmacist

license effective June 5, 2009 providing he continue with his PRN-PRN

program.

Second: Kam Gandhi

Action: Passed Unanimously

### 6. General Counsel Report

Carolyn Cramer gave a legislative update. She noted that everything we were tracking has been signed by the Governor. The cancer drug donation bill passed and we will need to do some rule making on this. There were minor modifications to the prescription monitoring program and we will not need to do any rule making. The satellite pharmacy bill was amended to include rural settings for doctors to see patients remotely. Long term care facilities will be able to return drugs for re-dispensing. Pharmacists will be able to do blood glucose testing. The Board will be seeing regulation Workshops and Public Hearings to define these newly signed laws.

### 7. Executive Secretary Report:

- A. Financial Report
- B. Investment Report

The financial and investment reports were presented to the Boards satisfaction.

### C. Temporary Licenses

Mr. Pinson approved three temporary licenses since the last Board meeting.

### D. Staff Activities

- 1. Meetings
  - a. PT Committee (4/22)

We conducted another Pharmaceutical Technician Committee meeting and discussed the three issues they had sent to the Board and were pleased to learn that pharmaceutical technicians will now be responsible to obtain one CE on Nevada law presented by Board staff or by attending a Board meeting for the whole day, just like pharmacists.

### b. Telepharmacy/Telemedicine (4/23 & 4/28)

Meetings were held with the Nevada Health Center's staff exploring the details of both Telepharmacy and telemedicine.

#### c. NABP – Miami

One of the topics at the NABP annual meeting was problems with dispensing practitioners across the nation. Nevada is one of the few states that actually license them but most states do not. Mr. Pinson indicated the states that do not license prescribing physicians were very interested in learning how we operate to stop the questionable dispensing practices in their states.

- 2. Legislative Update
  - a. Hillerby Report

Mr. Pinson noted that Fred Hillerby's report was in the Board book. He also noted that the bill requiring a black box warning did not pass.

- E. Reports to Board
  - 1. Abuse of Emergency CII Rx Rule

There appears to be an abuse of the emergency CII prescription rule within the long-term care community. The DEA said long-term care facilities cannot abuse the emergency CII rule for their patients.

2. Ryan Haight Act

This act was passed by Congress and signed into law and will strengthen the prevention of illicit internet pharmacy practices.

3. Virginia PMP Hack

Larry Pinson reported on the security breach of the prescription monitoring program in Virginia. The hackers were demanding \$10,000,000.00 for return of the data. We did a security check of our system and we are OK. We are still trying to contract with McKesson. Otech was the company that Virginia was using when their computer system was compromised, which is the company we are currently using. We have blocked Otech from access to our data. If they need to make a change, they send it to Joanee Quirk on a CD.

### 4. Tech School Requirements

Previous Board discussions on the fact that past criminal activity and drug abuse may impact a tech school student's ability to get licensed prompted Mr. Pinson to contact David Perlman of the Nevada Commission on Post Secondary Education. Often the students were unaware of these circumstances until well into the program and after paying tuition. Mr. Perlman graciously responded by notifying all pharm tech schools that incoming students must be advised of the above, prior to beginning the program.

### 5. Temporary Regulations

The two temporary regulations that we had during this session of the legislature have been passed. One requiring pharmaceutical technicians to acquire one hour of Nevada law and amendments to the MDEG regulations. They will be heard again when LCB drafts language for permanent adoption. We are working on multiple ways of notifying pharmacies, pharmacists and pharmaceutical technicians of this new requirement.

### F. Board Related News

Because of the hysteria on the swine flu issue, Mr. Pinson advised the Board that he will bring a D and D item to them on disaster planning and asked the Board to be thinking of ideas and bring them to the July meeting. We have a framework in place now because of Keith Macdonald's forethought to put something together, but now we need to refine it.

Ray Seidlinger has been working on the AB128 re-ups. Mr. Seidlinger has had difficulty obtaining immunization data. Liz Macmenamin will be getting information to Mr. Seidlinger from the retail community. Immunization is more complex and time consuming than AB128 was.

Mr. Pinson introduced Mark Stechschulte who is a representative of Sharps. Mr. Stechschulte gave a presentation on expired medication disposal. Sharps provides containers for the drug disposal, when the container is full it is mailed via USPS to Sharps where the container is incinerated. Sharps does not open the containers, they go directly to the incinerator. The program does not allow controlled substance disposal. The containers are approved for shipment through the postal service.

### G. Activities Report

### 8. Personnel Review

- A. Personnel Evaluation and Salary Review
- B. Executive Secretary Evaluation

Larry Pinson gave the Board the CPI figures for them to make a determination about a salary increase. He advised that the Board is independent, self funded and solvent and can afford an increase. He presented the CPI with no merit recommendations. The Board was very complimentary of all Board staff and made the following motion:

### **Board Action:**

Motion: Keith Macdonald moved to accept the CPI for Board staff's salary increase.

Second: David Chan

Action: Passed Unanimously

9. Review and Approval of 2010 Board Meeting Dates

The Board approved the proposed 2010 Board meeting dates as presented.

### WORKSHOP

### 10. Proposed Regulation Amendment Workshop

1. **Amendment of Nevada Administrative Code 639.707** Counseling of Patients: Duties of pharmacist or intern pharmacist; documentation.

Carolyn Cramer noted that this was the recommendation Keith Macdonald had requested removal of the list of specific topics that need to be addressed during counseling. LCB would not allow that since statute requires the list but now we are trying to find language that will be appropriate and address Mr. Macdonald's issues. It was determined that adding the words "and may consider" to section 2 and 4 should satisfy Mr. Macdonald and the LCB. Ms. Cramer also indicated that she added black box language due to the recent legislation proposed this session. Mary Lau indicated that she did not like the term "black box" and it was specifically directed to doctors, not pharmacists. Mr. Pinson indicated that this is just a proactive step. There was discussion and it was determined that the black box warning was in the drug packaging insert where contraindications are indicated. Liz Macmenamin appeared and noted that the FDA considers it a "box" warning, not a "black box" warning and indicated that her members did not want reference to it in the counseling regs. Russ Smith, a pharmacist, appeared and advised how he approaches the black box issues when he counsels and points the patient to the package insert and advises them to read the therapeutic contraindications as they are more in depth. The Board determined that they wanted "and may consider" added to section two and change the language in 4(c) to add "box warnings".

### Board Action:

Motion: Leo Basch moved to bring this language to Public Hearing with the

changes discussed.

Second: Chad Luebke

Action: Passed Unanimously

2. **Amendment of Nevada Administrative Code 639.7125** Use of fulfillment pharmacy by dispensing pharmacy.

Carolyn Cramer explained that the language presented was the result of the input from the Fulfillment Committee. Liz Macmenamin, representing RAN, Bill Okuna and Jim Palm, both representing Raley's gave input regarding the language presented by Board staff. Ms. Macmenamin had concerns regarding the NDC codes and why the language still included that requirement. Mr. Pinson advised that the NDC code identifies the drug and if there is a recall, it would be necessary to identify the drugs that were dispensed. This was an issue from Cookie Quandt who represented Long's and she is no longer employed with Long's since CVS bought the chain. Mr. Pinson noted that he did not think CVS was going to use fulfillment pharmacies and Mr. Luebke confirmed this so it is not an issue. Mr. Okuna noted that he thought in section II (f) "pharmacy personnel" was going to be substituted for "pharmaceutical technician". Mr. Pinson advised that he did not think it was appropriate for a clerk to do the verification process. After discussion staff was given direction and a motion was made.

### **Board Action:**

Motion: Mary Lau moved to approve with changes and bring to Public Hearing.

Second: Leo Basch

Action: Passed Unanimously

3. **Amendment of Nevada Administrative Code 639.694** MDEG Administrator required.

The Board discussed the language as presented and found it to be an accurate representation of what was necessary for an applicant to be a facility administrator in an MDEG facility.

### **Board Action:**

Motion: Mary Lau moved to take this regulation to Public Hearing.

Second: David Chan

Action: Passed Unanimously

 Amendment of Nevada Administrative Code 639.725 Use of mechanical counting devise for dispensing medications to be taken orally.

After discussion and input from Liz Macmenamin and Robert Mai it was determined to abandon further consideration of this regulation amendment.

### **Board Action:**

Motion: Chad Luebke moved to abandon this regulation amendment.

Second: Leo Basch

Action: Passed Unanimously

5. **Amendment of Nevada Administrative Code 639.528** Preparation and storage of food in prescription department of pharmacy.

Carolyn Cramer advised that this is a staff initiated request resulting from an issue brought up by Ray Seidlinger while he was inspecting a pharmacy. He found food in the refrigerator where drugs were stored. It was noted that Arkansas has passed regulations prohibiting food in pharmacy refrigerator's where drugs are stored. Further research found that the Joint Commission does not allow food storage in a refrigerator containing drugs in the hospital setting. Board inspectors have found horrible things in refrigerators and feel it would be best if food and drinks were kept in separate refrigerators from pharmacy drugs. Chad Luebke clarified that the food kept in the pharmacy would be for pharmacy personnel's own consumption and suggested that "for his own personal consumption" be left in the language.

### **Board Action:**

Motion: Chad Luebke moved to bring this amendment to Public Hearing with the

suggested change.

Second: Mary Lau

Action: Passed Unanimously

Mary Lau requested that the Public Hearing on these topics be held in September so she could participate since she was not going to be present for the July Board meeting.

11. Next Board Meeting:

July 15-16, 2009 - Las Vegas

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

There were no public comments.