

January 4, 2010

AGENDA

◆ PUBLIC NOTICE ◆

NEVADA STATE BOARD OF PHARMACY

BOARD MEETING

at the

Las Vegas Chamber of Commerce  
Turnberry Town Square  
6671 Las Vegas Boulevard, South  
Building D1, Suite 300  
Las Vegas

Wednesday, January 13, 2010 – 9:00 am

Thursday, January 14, 2010 – 9:00 am

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

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

◆ CONSENT AGENDA ◆

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

## January 2010 Board Meeting Agenda

- \* 1. [Approval of December 2-3, 2009, Minutes](#)
- \* 2. [Applications for Out-of-State MDEG – Non Appearance:](#)

- A. Binson's Hospital Supplies, Inc. – Center Line, MI
- B. Orbit Medical of Indiana, Inc. – Indianapolis, IN
- C. National Seating & Mobility, Inc. – Sacramento, CA
- D. North Coast Medical Supply – Carlsbad, CA
- E. PharMerica – Smyrna, GA
- F. Sanvita CBGM, LLC – Bedford, MA
- G. Symbios Medical, LLC – Phoenix, AZ

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

- H. Costco Wholesale Corporation – Corona, CA
- I. Depot Drug – Salt Lake City, UT
- J. Griff's Compounding Center, Inc. – Scottsbluff, NE
- K. Express Scripts, Inc. – Phoenix, AZ
- L. Lee Silsby Compounding Pharmacy – Cleveland Heights, OH
- M. Precision Pharmacy – Bakersfield, CA
- N. Preferred Rx, LLC – Arlington, TX

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

- O. Aidapak Services, LLC – Vancouver, WA
- P. Bioform Medical, Inc. – Franksville, WI
- Q. Butler Schein Animal Health Supply – Columbus, OH
- R. Butler Schein Animal Health Supply – Salt Lake City, UT
- S. Butler Schein Animal Health Supply – Tualatin, OR
- T. Butler Schein Animal Health Supply – Visalia, CA
- U. Cardinal Health – Valencia, CA
- V. DeRoyal Industries, Inc. – New Tazewell, TN
- W. Fresenius Medical Care North America – Los Lunas, NM
- X. Glenwood-LLC – Englewood, NJ
- Y. Medicis Aesthetics, Inc. – Scottsdale, AZ
- Z. Medicis, The Dermatology Company – Scottsdale, AZ
- AA. Owens & Minor Healthcare Logistics – Louisville, KY
- BB. Physicians' Pharmaceutical Corporation – Oak Ridge, TN
- CC. Promotech – Totowa, NJ
- DD. Ucyglyd Pharma, Inc. – Scottsdale, AZ

### Applications for Nevada MDEG – Non Appearance:

- EE. Hathaway Medical – Las Vegas
- FF. True Pharmacy – Las Vegas
- GG. Zee Medical Service Company – Las Vegas

## January 2010 Board Meeting Agenda

### Applications for Nevada Pharmacy – Non Appearance:

- HH. BHS Specialty Pharmacy – Las Vegas
- II. Horizon Surgical Center – Henderson
- JJ. Metro Drugs – Las Vegas
- KK. Nevada Drug Compounding Pharmacy East – Henderson
- LL. Nevada Drug Compounding Pharmacy West – Las Vegas
- MM. Remedy Rx – Las Vegas
- NN. Smoke Ranch Surgery Center – Las Vegas
- OO. True Pharmacy – Las Vegas

### ◆ REGULAR AGENDA ◆

- \* 3. [Disciplinary Actions: Note](#) – The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties.
  - A. Warren C. Rolen, R.Ph (09-040-RPH-S)
  - B. Mountain View Pharmacy (09-040-PH-S)
  - C. William C. Colton, PTT (09-107-PTT-S)
  - D. Julie E. Wells, PT (09-113-PT-S)
- \* 4. [Requests for Pharmaceutical Technician in Training License – Appearance:](#)
  - A. Anzon Pablo
  - B. Genero Siciliano
- \* 5. [Request for Pharmacist License – Examinee – Appearance:](#)
  - David Katsules
- \* 6. [Request for Pharmacist License – Reciprocal – Appearance:](#)
  - Madonna Wilcox
- \* 7. [Request for Reinstatement of Pharmacist License – Appearance:](#)
  - Zachary W. Bergan (07-083-RPH-N)
- \* 8. [Application for Out-of-State Pharmacy – Appearance:](#)
  - Altius Healthcare – Prescott, AZ
- \* 9. Your Success Report:
  - Burke's Drug

## January 2010 Board Meeting Agenda

\*10. Presentation:

[Preparing for Regulatory Inspectors & Inspecting for Safety](#)

Larry Pinson & Katie Johnson

\*11. [General Counsel Report:](#)

Sanchez v. Wal-Mart

\*12. [Executive Secretary Report:](#)

- A. Financial Report
- B. Investment Report
- C. Temporary Licenses
- D. Staff Activities
- E. Reports to Board
- F. Activities Report

\*13. [Discussion and Determination:](#)

- A. Refrigerator Log
- B. Scheduling of Propofol as a Controlled Substance
- C. Scheduling of Lisdexamfetamine, Lacosamide and Tapentadol as Controlled Substances

W O R K S H O P – Thursday, January 14, 2010 – 9:00 am

\*14. [Discussion:](#)

**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.

**Amendment of Nevada Administrative Code 639.NEW Telepharmacy Regulation** This language sets the parameters for a pharmacist or dispensing practitioner to practice from a remote site.

15. Next Board Meeting:

March 3 & 4, 2010 – Reno, Nevada

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

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

\* Board action may be taken on these items.



## January 2010 Board Meeting Agenda

Note: We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements for the meeting are necessary, please notify the Nevada State Board of Pharmacy, 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.

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 full day to receive CE credit including the law credit.

This notice has been posted at the following locations and is available for viewing at [bop.nv.gov](http://bop.nv.gov):

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

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## BOARD MEETING

at the

Airport Plaza Hotel  
1981 Terminal Way  
Reno

December 2<sup>nd</sup> and 3<sup>rd</sup>, 2009

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

### Board Members Present:

Keith Macdonald  
Donald Fey  
Mary Lau

Beth Foster  
Chad Luebke

Kirk Wentworth  
Kam Gandhi

### Board Members Absent:

### Board Staff Present:

Larry Pinson

Jeri Walter

Carolyn Cramer

Keith Marcher

## CONSENT AGENDA

1. Approval of October 14-15, 2009, Minutes
2. Applications for Out-of-State MDEG – Non Appearance:
  - A. 180 Medical, Inc. – Oklahoma City, OK
  - B. American Diabetic Assistance – Coral Springs, FL
  - C. Kalisthenics, Inc. – Buena Park, CA
  - D. Medico Express, Inc. – Miami, FL
  - E. NE Ohio Health & Home Solutions – Wickliffe, OH
  - F. Oxford Diabetic Supply Inc. – New York, NY
  - G. Rehab Systems Inc. – Twin Falls, ID

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

- H. Agropec Trading, Inc. – Hialeah, FL
- I. Bell Plaza Pharmacy – Bell, CA
- J. California Pharmacy & Compounding Center – Newport Beach, CA
- K. Easy Scripts, Inc. – Chicago, IL
- L. Medco Health Solutions of Indiana, LLC – Whitestown, IN
- M. PMSI – Tampa, FL

- M. PMSI – Tampa, FL
- N. RSF Pharmaceuticals – San Marcos, CA
- O. Select Rx – Chalfont, PA
- P. Wickcliffe Veterinary Pharmacy – Lexington, KY

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

- Q. Allocation Inc. – Park Ridge, NJ
- R. Amylin Ohio, LLC – Hamilton, OH
- S. Antigen Laboratories, Inc. – Liberty, MO
- T. Associated Pharmacies, Inc. – Scottsboro, AL
- U. Cardinal Health – Denver, CO
- V. Foundation Care LLC – Earth City, MO
- W. KCI USA, Inc. – Pittston, PA
- X. Slate Pharmaceuticals, Inc. – Durham, NC
- Y. Virbac AH, Inc. – Bridgeton, MO
- Z. Webster Veterinary Supply, Inc. – Phoenix, AZ

Applications for Nevada Pharmacy – Non Appearance:

- AA. Cardinal Health 414, LLC – Las Vegas
- BB. Nevada Drug Compounding Pharmacy East – Henderson
- CC. Nevada Drug Compounding Pharmacy West – Las Vegas
- DD. Unique Care Pharmacy Inc. – Las Vegas
- EE. Walgreens #10862 – Las Vegas
- FF. Walgreens #11668 – Las Vegas
- GG. Walgreens #12540 – Sparks

Application for Nevada MDEG – Non Appearance:

- HH. Unique Care Pharmacy Inc. – Las Vegas

Discussion:

The consent agenda applications and supporting documents were reviewed. Larry Pinson asked that BB and CC be pulled from the vote for discussion.

NOTE: Mary Lau was delayed and was not present to vote on the Consent Agenda.

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 BB and CC.

Second: Chad Luebke

Action: Passed Unanimously.

Motion: Chad Luebke found the minutes to accurate and complete and moved for approval.

Second: Kam Gandhi

Action: Passed Unanimously.

Discussion:

Carolyn Cramer noted that there were discrepancies on the applications from Nevada Compounding Pharmacy East and West. One indicated that someone in their organization had a misdemeanor or felony and the other did not. The one that indicated they had a misdemeanor or felony did not provide any details as required.

Motion: Kam Gandhi moved to table the applications until clarification was provided to Board staff.

Second: Keith Macdonald

Action: Passed Unanimously

### REGULAR AGENDA

#### 3. Reconsideration of Board Order – Appearance:

Davidson Okpukpara, R.Ph

(09-054-RPH-N)

Davidson Okpukpara appeared and was sworn by President Fey prior to answering questions or offering testimony.

NOTE: Mary Lau recused from participation as Mr. Okpukpara works for one of the pharmacies that belong to RAN.

Mr. Okpukpara advised the Board that this was his last week practicing as an intern pharmacist as directed in his Order. Mr. Okpukpara asked the Board to consider reducing the fine that was imposed in the referenced case because he had already taken a drastic pay cut for practicing as an intern and it has become a hardship on his family. He also requested the length of probation be shortened and asked that he be allowed to practice as a managing pharmacist.

Mr. Okpukpara gave a review of his career and apologized for errors happening when he was on duty. He feels that he is being punished again for his first error which was more serious than the one in the referenced case, yet he is being more severely punished and asked the Board for leniency.

The Board asked Mr. Okpukpara why it was important for him to be a managing pharmacist. He indicated that when he went to work at Raley's in Winnemucca as their managing pharmacist, he was to help make the pharmacy more efficient and orderly and he would like to continue with those responsibilities. Mr. Okpukpara indicated that he has learned from his experience of practicing as an intern pharmacist that he needs to focus on his job and not let distractions interfere with his practice. He stated that he has set up new guidelines for the practice of pharmacy for himself and the staff from the lessons he has learned from this experience.

Keith Macdonald indicated that he thinks the fine imposed upon Mr. Okpukpara for a non-ingested error was excessive and disallowing him to practice as a managing pharmacist for three years is too long.

Chad Luebke noted that originally he felt that Mr. Okpukpara had issues taking ownership of the error in this matter. Mr. Luebke indicated that he now feels that his internship has allowed him to reflect and accept responsibility for his actions.

Mr. Macdonald suggested that we reduce the fine to \$1,000.00 and when Mr. Okpukpara needs to perform as a managing pharmacist have him make the request at that time. Mr. Okpukpara indicated that he can still perform pharmacist duties and set up guidelines for the store without being a managing pharmacist at this time.

After a failed motion, the following motion was passed:

Board Action:

Motion: Kam Gandhi moved to reduce the fine from \$3,000.00 to \$1,500.00 plus fees and costs, allow Mr. Okpukpara to pay the fine and fees within six months rather than 90 days and amend his Order further to allow Mr. Okpukpara to practice as a managing pharmacist.

Second: Keith Macdonald

Action: Passed With One Negative Vote

4. Disciplinary Actions:

- |    |                      |                |
|----|----------------------|----------------|
| A. | Virginia Agha, R.Ph  | (09-065-RPH-N) |
| B. | Costco Pharmacy #646 | (09-065-PH-N)  |

Warren Wong, district pharmacy manager for Costco, Virginia Agha, Rita Middleton, complainant, and Joe Depczynski, Board investigator, appeared and were sworn by President Fey prior to answering questions or offering testimony.

Carolyn Cramer called Joe Depczynski to testify on this matter. Mr. Depczynski described the procedures he follows when doing an investigation. Mr. Depczynski explained what he learned in this instance. A pharmaceutical technician received the

prescription for Elavil 10 mg. tablets from Ms. Middleton and input it into the Costco computer system. The pharmaceutical technician used a dropdown list to choose the generic substitution for Elavil and in so doing she chose the wrong strength. After input, the prescription was going to be sent to a central fill facility for filling. Ms. Agha was the confirming pharmacist on this prescription and checked it before it went to the central fill facility. Ms. Agha did not look at the original prescription. The central fill facility does not see the original prescription so they filled from what they received from the pharmacy. Mr. Depczynski also indicated that there was no indication on the counseling log that counseling had taken place. Ultimately, Ms. Middleton received 100 mg. tablets of generic Elavil rather than the 10 mg. tablets her physician prescribed.

Rita Middleton testified that she received her prescription from Costco and began taking the medication she was given. Ms. Middleton stated that she slept for three days and went to the hospital and had an EKG and other tests. Ms. Cramer asked Ms. Middleton if she was counseled when she picked up her medication and she indicated that Ms. Agha advised her to take one tablet at bedtime but nothing more. Ms. Middleton made an appointment with her physician and questioned the dosage. It was at that time Ms. Middleton realized she was given 100 mg. generic Elavil rather than the 10 mg. tablets her physician prescribed.

Ms. Agha described her pharmacy practice and explained her normal counseling procedures. Ms. Agha indicated that she found it unusual that if she spoke with Ms. Middleton that she only told her to take one tablet at bedtime. There was lengthy discussion regarding the processing of prescriptions at Costco and their central fill facility. Ms. Agha admitted that they were not keeping accurate records of central fill prescriptions at the time this error occurred, however since this incident they have found a less cumbersome process to ensure the records were accurate. Ms. Agha indicated that they had only had their central fill facility for approximately two months at the time Ms. Middleton's prescription was filled.

Mr. Wong explained the changes they have made to circumvent this type of error from happening again, however he admitted that the central fill facility still does not have the ability to view original written prescriptions.

Carolyn Cramer made closing statements and gave recommendations.

Keith Macdonald voiced his concerns regarding the counseling charges. He indicated that a pharmacist cannot possibly go over all eight items in our regulations. Mr. Macdonald indicated he would like to dismiss the Second and Third Causes of Action since Ms. Middleton admitted that the pharmacist spoke with her. Having said that, Mr. Macdonald again reiterated that it was impossible to determine what defines the amount of counseling and what is appropriate. Mary Lau and Beth Foster agreed with Mr. Macdonald's suggestion.

#### Board Action:

Motion: Chad Luebke moved to find Ms. Agha guilty of the First Cause of Action.

Second: Keith Macdonald

Action: Passed Unanimously

Motion: Chad Luebke moved to fine Ms. Agha \$1,000.00 for the error in the First Cause of Action.

Second: Beth Foster

Action: Passed With One Negative Vote

Motion: Chad Luebke moved to find Ms. Agha not guilty of the Second Cause of Action.

Second: Keith Macdonald

Action: Passed Unanimously

Motion: Chad Luebke moved to find Costco guilty of the Third Cause of Action.

Second: Keith Macdonald

Action: Passed Unanimously

Motion: Chad Luebke moved to fine Costco \$750.00 for the Third Cause of Action regarding counseling.

Second: Keith Macdonald

Action: Passed Unanimously

Motion: Chad Luebke moved to find Costco guilty of the Fourth Cause of Action.

Second: Beth Foster

Action: Passed Unanimously

Motion: Chad Luebke moved to have Costco meet with Board staff to review their counseling records.

Second: Mary Lau

Action: Passed Unanimously

Motion: Chad Luebke moved to have Ms. Agha and Costco split the fees and costs in this matter.

Second: Kam Gandhi

Action: Passed Unanimously

C. Kevin L. Green, PTT (09-074-PT-N)

Carolyn Cramer noted that Mr. Green was notified of the time and place of the hearing however he was not present.

Ms. Cramer noted that this was a termination of employment notice from Walgreens #04789. Mr. Green had been terminated from employment for diversion of dangerous drugs, namely 30 tablets of Tramadol and a two month supply of Ocella birth control pills. Mr. Green also diverted controlled substances, namely 300 Percocet 10/325 mg. tablets.

Board Action:

Motion: Keith Macdonald moved to find Mr. Green guilty of the First and Second Causes of Action.

Second: Kam Gandhi

Action: Passed Unanimously

Motion: Keith Macdonald moved to revoke Mr. Green's pharmaceutical technician in training registration.

Second: Kam Gandhi

Action: Passed Unanimously

D. Kevin O'Neil Jr, R.Ph (09-069-RPH-N)  
E. Wal-Mart Pharmacy #10-3408 (09-069-PH-N)

NOTE: Keith Macdonald recused from participation in this matter as he is employed by Wal-Mart and Mary Lau recused because Wal-Mart is a member of RAN.

Debbie Mack appeared for Wal-Mart and Hal Taylor was present as local legal counsel for Wal-Mart. Mr. O'Neil represented himself.

Carolyn Cramer advised the Board that all parties had stipulated to the facts of this matter and made a recommendation for all three Causes of Action. She recommended a fine of \$1,000.00 for the First Cause of Action regarding the error made by Mr. O'Neil, a fine of \$750.00 for the Second Cause of Action regarding failure to counsel for Mr. O'Neil, and Board Staff to meet with Wal-Mart regarding their counseling issues for the Third and Fourth Causes of Action.



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

Mr. Depczynski gave a synopsis of his investigation into this matter. Glenn Ladd, the complainant, took a new prescription for four 50,000 IU vitamin D capsules to Wal-Mart to be filled. Mr. Depczynski found during his investigation that a pharmaceutical technician input the prescription into the pharmacy computer however inadvertently entered the wrong directions causing Mr. Ladd to take 50,000 IU vitamin D tablets daily for four days rather than one a week. Mr. O'Neal was the pharmacist that verified the work of the pharmaceutical technician and did not notice that the directions were incorrect. Mr. Depczynski reviewed the counseling records and they showed that Mr. Ladd refused counseling 18 minutes after he purchased the prescription.

Glenn Ladd appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Ladd gave details of what he experienced as the result of taking too much vitamin D. He explained that he has a heart condition and he suffered from nausea, stomach cramps, diarrhea, loss of appetite, dry mouth, insomnia, headaches and rapid heartbeat and heart fluttering. Mr. Ladd's cardiologist prescribed medication to help regulate his heartbeat.

Mr. O'Neil asked Mr. Ladd if he had lab work done and what the levels were. Mr. Ladd responded that he had lab work done, however by the time the labs were done his vitamin D levels were almost normal.

Kevin O'Neil appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. O'Neil explained that he had researched vitamin D levels and found common dosing quantities and stated that he did not believe the amount that Mr. Ladd had ingested could have done harm. Mr. O'Neil presented a packet of redacted prescriptions showing common quantities prescribed by local physicians that the dosages were as high as Mr. Ladd had ingested and higher. The packet was marked as Exhibit A and admitted into the record.

Mr. Taylor presented a screen shot showing how the Wal-Mart computer system is set up in Arizona when counseling is required. The screen shot was marked Exhibit B and accepted into the record.

Ms. Cramer indicated that Board staff was anxious to sit down with Wal-Mart and work out a solution to ensure their counseling records are accurate and reflect the real time counseling was accepted or refused.

Mr. Taylor gave closing remarks and noted that he is comfortable that the recommendation made by Ms. Cramer was appropriate.

After Board discussion and agreement with counsel it was agreed that for the First Cause of Action against Mr. O'Neil he will be fined \$1,000.00 for the error. The Second Cause of Action against Mr. O'Neil is dismissed. On the Third Cause of Action there is no contest from Wal-Mart for failing to maintain counseling records accurately and will pay a fine of \$750.00. For the Fourth Cause of Action for Wal-Mart owning and operating the pharmacy in which the error occurred, Wal-Mart will meet with Board staff to resolve the counseling record issue.

Board Action:

Motion: Kam Gandhi moved to accept the stipulated agreement as presented.

Second: Beth Foster

Action: Passed Unanimously

After this hearing, Keith Macdonald stated that he wanted to discuss counseling. He indicated that he is frustrated with the whole counseling issue. He is aware that each chain store has their own method of tracking counseling, but stated that he wants an interpretation of what "immediately documented" in our law means. Chad Luebke said there must be a way to come to a meaningful compromise between Nevada law and how each chain handles documentation of counseling. Mr. Macdonald stated that he would like our law to say what we mean.

The Board directed staff to put the counseling issue on the January agenda as a Discussion and Determination item.

F. Scott W. Bainbridge, R.Ph (09-075-RPH-O)

Carolyn Cramer advised the Board that Mr. Bainbridge had signed a stipulated agreement relinquishing his pharmacist license in Nevada to parallel an action taken in the state of Iowa. Mr. Bainbridge was on probation in Iowa and he violated his probation by consuming alcohol and failing to file monthly reports with the Iowa Board of Pharmacy.

Board Action:

Motion: Chad Luebke moved to accept the Stipulated agreement.

Second: Kam Gandhi

Action: Passed Unanimously

5. Request for Pharmacist License – Reciprocity – Appearance:

Madonna R. Wilcox, R.Ph

Ms. Wilcox cancelled her appearance and will reschedule.

6. Application for Nevada Manufacturer – Appearance:

Central Admixture Pharmacy Services Inc. – Las Vegas

Bill Jones appeared and was sworn by President Fey prior to answering questions or offering testimony.

Larry Pinson reviewed the CAPS application process for the new Board members. They are applying for a manufacturing license, however have been unable to provide proof to Board staff that they are licensed as a manufacturer with the FDA.

Mr. Jones read a correspondence from the FDA. He conceded that the circumstances are unusual, but even the FDA cannot provide a “certificate” for the location they are trying to license with our Board. Through an intricate history of e-mails between a representative from the FDA and Mr. Jones and one of his associates, the FDA representative cannot be certain when their facility will show on the FDA Drug Registration Listing System. The Board asked Mr. Jones if their other locations show on the FDA system and they all do, except for this specific location which they are assured will show eventually.

Board Action:

Motion: Keith moved to approve the application for CAPS.

Second: Chad Luebke

Action: Passed Unanimously

Mr. Jones thanked the Board and advised that he would keep in touch with Board staff as to their progress of getting this facility on the FDA verification list.

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

Rachel L. May

Rachel May appeared and was sworn by President Fey prior to answering questions or offering testimony.

Carolyn Cramer advised that Ms. May had answered the question regarding having been charged, arrested or convicted of a misdemeanor or felony in the affirmative on her pharmaceutical technician in training application. Ms. May is present to answer questions from the Board.

Ms. May was very matter of fact. She admitted that she had been arrested for driving under the influence of alcohol but claimed that she is not alcohol dependent. In fact, she is diabetic and generally does not drink. Ms. May indicated that all of the charges have been dropped against her. Ms. May was asked why she wanted to be a pharmaceutical technician and she indicated that she was an EMT for a long time but would rather be a pharmaceutical technician because she does not want to touch people but would like to help people nonetheless. Ms. May indicated that she has a B average at CCNN and would like to complete the program by obtaining her pharmaceutical technician in training registration so she can work in a pharmacy. Ms. May was asked if she would be open to having a PRN-PRN evaluation and she indicated that she would.

Board Action:

Motion: Chad Luebke moved to approve Ms. May's application for pharmaceutical technician in training and require her to have a PRN-PRN evaluation.

Second: Kam Gandhi

Action: Passed With One Negative Vote

8. Applications for Nevada Pharmacy – Appearance:

A. Clark County Pharmaceutical Services – Las Vegas

William Dahlberg appeared and was sworn by President Fey prior to answering questions or offering testimony.

Carolyn Cramer reviewed the application process with Clark County Pharmaceutical Services to date. At the last meeting the application was tabled and Roy Beal and William Dahlberg were asked to meet with Board staff to come up with some conditions they would be willing to abide by if their application were approved. Ms. Cramer indicated that Board staff still did not recommend approval of this application.

Larry Pinson reviewed the list of seven conditions they came up with, including providing copies of contracts with clients and suppliers, providing copies of un-redacted purchases and sales, the pharmacy will provide purple sheets on a monthly basis, there will be no change in their corporate structure or pharmacy management without prior approval and paramount to the agreement, they would not be authorized to deal in MDEG products for a period of one year.

Mr. Dahlberg stated that Board staff did not have the correct information regarding the timeline of Mr. Dahlberg and Mr. Beal's activities with previous business entities. He stated that they have agreed to the conditions structured at the meeting with the Board's staff and they plan to do business as upstanding citizens in the Las Vegas area and request approval of their application for a sole proprietor pharmacy license.

Board Action:

Motion: Keith Macdonald moved to approve the application with the conditions Mr. Dahlberg and Mr. Beal agreed to.

Second: No Second

Action: Motion Failed

Motion: Chad Luebke moved to deny the application.

Second: Mary Lau

Action: Passed with One Negative Vote

Mr. Dahlberg questioned the Board regarding their decision to deny the application. He demanded specific reasons why Mr. Luebke and Ms. Lau made the motion to deny. After discussion the Board tried another motion.

Motion: Kirk Wentworth moved to reconsider the first motion.

Second: Keith Macdonald

Action: Motion Failed With 4 Negative Votes

B. Ridley's Pharmacy #1154 – Ely

John W. Condry, risk manager for Ridley's, appeared and was sworn by President Fey prior to answering questions or offering testimony.

NOTE: Mary Lau recused from participation in this matter.

Mr. Condry advised the Board that two years ago Ridley's purchased Gorman's grocery store in Ely but the grocery store did not have a pharmacy. They purchased Step Toe Pharmacy from Art Olson and eventually they will be moving the pharmacy into the grocery store. At the moment Mr. Olson is staying on as the managing pharmacist and to help with the transition. Currently Ridley's owns thirteen grocery stores in Idaho, Wyoming and Utah and ten of those grocery stores have pharmacies, so they are aware of how to go about adding the pharmacy to Gorman's grocery store.

Board Action:

Motion: Kam Gandhi moved to approve the application for pharmacy for Ridley's.

Second: Keith Macdonald

Action: Passed Unanimously

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

- A. BioRx – Urbandale, IA
- B. Walgreens Specialty Infusion Pharmacy – Lombard, IL

No one appeared for BioRx or Walgreens Specialty Infusion Pharmacy.

Board Action:

Motion: Kam Gandhi moved to table the applications for BioRx and Walgreens Specialty Infusion Pharmacy.

Second: Beth Foster

Action: Passed Unanimously

10. Application for Out-of-State MDEG – Appearance:

In Home Rx – San Marcos, CA

Dennis Karnes, president, appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Karnes gave a description of his business plan. He is applying for an out of state MDEG license so he can ship from California to Nevada patients.

Carolyn Cramer advised the Board that Mr. Karnes is already operating in Nevada and asked Ray Seidlinger to come forward.

Ray Seidlinger, Board inspector, appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Seidlinger stated that he went to 4320 West Reno #C in Las Vegas to inspect Arise Medical, Inc. When he arrived he was informed that it was not Arise Medical now, but it is Three Wishes. The person at Arise/Three Wishes told Mr. Seidlinger that Three Wishes ships to 4320 West Reno #C in Las Vegas from their facility in California and do not ship directly to patients.

After discussion with the Board, Mr. Karnes withdrew his application.

11. Election of Treasurer

Board Action:

Motion: Kam Gandhi moved to elect Keith Macdonald as Treasurer for the Board.

Second: Chad Luebke

Action: Passed Unanimously

12. General Counsel Report

Carolyn Cramer advised the Board that she attended the ASPL conference and related some of the highlights. One topic was the Chinese heparin issue in pet food and baby formula. The plant where the filler was made had a process that could not identify if a product was adulterated when tested. The United States sent the FDA to China to investigate but by the time they got there they had executed the plant executive and bulldozed the plant and told the FDA officers there was no more problem.

As follow up to the request for a decrease in wholesaler's surety bonds, she found that J. Knipper was a publicly traded company and did not need to provide a bond. Since then another company has come forth and made a request for a decrease in their bond. Ms. Cramer read a portion of the law that describes who would qualify for a decrease and asked the Board to give her and Larry Pinson the authority to determine if a decrease could be granted.

Board Action:

Motion: Keith Macdonald moved to grant authority to Larry Pinson and Carolyn Cramer to determine if a wholesaler would qualify for a decrease in their bond requirement.

Second: Kam Gandhi

Action: Passed Unanimously

13. Executive Secretary Report:

- A. Financial Report
- B. Investment Report
- C. Audit – Fiscal 2009

Larry Pinson gave the financial and investment reports to the Board's satisfaction and presented the 2009 audit.

- D. Temporary Licenses

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

- E. Staff Activities

1. CE Programs

- a. Development of program with Your Success (12/11)

Mr. Pinson advised that he and Katie Johnson developed a slide show that they will present at live CE's. He noted that it is a valuable tool and should enlighten pharmacists about how their environment can affect their practice. They will give their first presentation at Scolari's on December 11<sup>th</sup>.

## 2. Law and Ethics Class – Sacramento

Mr. Pinson spoke to a group of pharmacy students at California North State College of Pharmacy in Rancho Cordova. He noted that their tuition is \$40,000.00 per year for a four year course of study.

## 3. Renewals

Renewals ran extremely smoothly this year. Board staff was able to keep up their regular duties as well as keep up with the renewal process.

## 4. Legislative Commission on Regulations Appearance (10/26)

Board staff appeared before the Legislative Commission and all of our regulations passed.

## 5. Interim Health Committee Appearance (11/4)

Mr. Pinson appeared before the Interim Health Committee and spoke on prescription drug abuse. He stated that he has also been invited to speak at the dental society and before the Board of Osteopathic Medicine.

### F. Reports to Board

#### 1. Financial Disclosure

The Board was asked to complete the financial disclosure form for the Board's records.

#### 2. Report to Legislature on AB 446 (2007 Session)

Mr. Pinson presented the report to the legislature on implementation of AB446 regarding the tracking of prescriptions for controlled substances.

#### 3. Expenses handout

The Board was given the 2010 Per Diem Rates for Meals and Incidental Expenses.

### G. Board Related News

#### 1. ICPT

Mr. Pinson directed the Board to a letter from NABP indicating that ICPT had been sold or had transferred ownership. NABP will keep the Board's apprised if there are any changes in the ICPT program that would need to be addressed. NABP is in the process of obtaining information on the new owners to ensure the examination and credentialing process satisfies the same standards as originally approved,

### H. Activities Report

## WORKSHOP

### 14. **Proposed Regulation Amendment Workshop**

#### 1. **Amendment of Nevada Administrative Code 639.945 Bona Fide Therapeutic Relationship**

Carolyn Cramer advised the Board that Mike Pavlakis of Allison MacKenzie submitted a letter and advised that the language as drafted meets the concerns they raised at the September Board meeting regarding a doctor/patient relationship in correctional facilities.

Ms. Cramer reviewed the genesis of this concept for the new Board members. This is our first attempt at getting something in regulation to allow telemedicine as an option in the correctional facility arena. She indicated that the Legislative Counsel Bureau may



not allow it because law specifies that a bona fide relationship is where the doctor “physically” examines a patient.

President Fey noted that he has difficulty with the term “offenders” rather than using the term patient. Ms. Cramer explained that in a correctional facility the patients are offenders and that is what LCB calls them.

It was suggested that in 4(c) we add APN to the group of people employed in a correctional institution that can be trained in the use of videoconferencing equipment.

Board Action:

Motion: Keith Macdonald moved to make the correction as noted and bring to Public Hearing.

Second: Kam Gandhi

Action: Passed Unanimously

**2. Amendment of Nevada Administrative Code AB213 Cancer Drug Donation Program.**

Patty Halterman, representing the Nevada Cancer Institute appeared with questions regarding the donation program and if it would have a central repository and the answer to that was no – the participants would be on their own. This is a voluntary program and each pharmacy that elected to participate would set up their own system of handling the drugs, and issuing them. Ms. Halterman asked about patient consent and Board staff noted that that was addressed in the final draft of AB213. Ms. Halterman thanked the Board for clarification.

Board Action:

Motion: Keith Macdonald moved to bring these regulations to Public Hearing.

Second: Kirk Wentworth

Action: Passed Unanimously

**3. Amendment of Nevada Administrative Code 639.7125 Use of fulfillment pharmacy by dispensing pharmacy.** Twofold: 1) To allow a registered mail order pharmacy to act as a fulfillment pharmacy, and 2) to better regulate and clarify the practices of a fulfillment pharmacy with respect to consumer understanding and patient safety.

Liz Macmenamin, representing RAN and Jeff Sinko, representing Medco appeared and presented objection to section 8 as written. Ms. Macmenamin and Mr. Sinko asked the Board to remove section 8(2) and (c) from the language after citing various reasons.

The Board discussed and agreed that that change would be in the best interest for all concerned.

Board Action:

Motion: Mary Lau moved to approve as rewritten and delete section 8(2) and (c) as discussed.

Second: Keith Macdonald

Action: Passed Unanimously

PUBLIC HEARING

15. Notice of Intent to Act Upon a Regulation:

1. **Amendment of Nevada Administrative Codes 453.530 Schedule III and 453.550 Schedule V** The Board is removing buprenorphine from Schedule V (453.530) and adding buprenorphine to Schedule III (453.530) to parallel federal law.

President Fey opened the Public Hearing.

There was no public comment.

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

Board Action:

Motion: Keith Macdonald moved to adopt these regulations as presented.

Second: Kam Gandhi

Action: Passed Unanimously

2. **Amendment of Nevada Administrative Code 639.272 Requirements for Physicians Assistant registration.** This amendment will delete the requirement for a physician's assistant to have a relationship with a consultant pharmacist since they are already under the direct supervision of their collaborating physician.

President Fey opened the Public Hearing.

There was no public comment.

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

Board Action:

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

Second: Keith Macdonald

Action: Passed Unanimously

3. **Amendment of Nevada Administrative Code 639.220 Schedule of Fees.** The language will increase the registration fee and renewal fee for pharmacists from \$150.00 to \$180.00 and the registration fee and renewal fee for intern pharmacists from \$15.00 to \$40.00. The Board has not increased fees for pharmacists since 2001 or for interns since 1995. The cost of doing business has increased, however by increasing these fees it will allow Board staff to continue to serve licensees in a professional timely manner.

The Board discussed increasing the fees for pharmacists and interns. Mary Lau indicated that she did not want to raise fees in this economic time of uncertainty.

President Fey opened the Public Hearing.

Ed Smith, representing CVS, appeared and was sworn by President Fey prior to answering questions or offering testimony.

Mr. Smith supported the increase in pharmacists licensing and renewal fees but felt that interns fees should remain the same.

President Fey closed the Public Hearing and asked for discussion or a motion.

Board Action:

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

Second: Kirk Wentworth

Action: Passed With One Negative Vote

4. **Amendment of Nevada Administrative Code 639.870 Requirements for Advanced Practitioner of Nursing registration.** This amendment will delete the requirement for an advanced practitioner of nursing to have a relationship with a consultant pharmacist since they are already under the direct supervision of their collaborating physician

President Fey opened the Public Hearing.

There was no public comment.

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

Board Action:

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

Second: Kam Gandhi

Action: Passed Unanimously

16 Next Board Meeting:

January 13 & 14, 2010 – Las Vegas, Nevada

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

There was no public comment.

Blank

# NEVADA STATE BOARD OF PHARMACY

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

## APPLICATION FOR OUT-OF-STATE MDEG PROVIDER 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 MDEG ☒ Ownership Change ☐ Name Change ☐ Location Change ☐

### FACILITY INFORMATION

Facility Name: BINSON'S Hospital Supplies, Inc.

Physical Address: 26834 LAWRENCE, E

(This must be a business address, we can not issue a license to a home address)

Mailing Address: \_\_\_\_\_

City: CENTER LINE State: MI Zip Code: 48015

Telephone Number: 586-755-2300 Fax Number: 586-755-2322

E-mail: jane.f@binsons.com Website: www.binsons.com

### DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8AM to 6PM Tue: 8AM to 6PM Wed: 8AM to 6PM Thu: 8AM to 6PM

Fri: 8AM to 6PM Sat: 9AM to 3PM Sun: after hour service - 24-7  
to Holidays: to

### FACILITY ADMINISTRATOR INFORMATION

Name: JAMES E BINSON II

Address: 26834 LAWRENCE

City: CENTER LINE State: MI Zip Code: 48015

### TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases

☐ Respiratory Equipment

☐ Life-sustaining equipment

☒ Diabetic Supplies

☐ Assistive Equipment

☐ Parenteral and Enteral Equipment

☐ Orthotics and Prosthesis

Other: \_\_\_\_\_

### Board Use Only

Received \_\_\_\_\_

Check Number

405

Amount

500.00

## NEVADA STATE BOARD OF PHARMACY

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

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 MDEG Provider ☒ Ownership Change ☐ Name Change ☐ Location Change ☐

#### FACILITY INFORMATION

Facility Name: Orbit Medical of Indiana, Inc.

Physical Address: 9402 Uptown Dr. Ste. 800 Indianapolis, IN 46256

Mailing Address: 716 E. 4500 S. Ste. 260

City: Salt Lake City State: UT Zip Code: 84107

Telephone Number: 801-713-2039 Fax Number: 801-713-5339

#### 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: Vaughn Evans

Address: 716 E. 4500 S. Ste. 260

City: Salt Lake City State: UT Zip Code: 84107

Telephone Number: 801-713-2039

#### TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)

☐ Medical Gases ☒ <sup>power wheelchairs</sup> 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 \_\_\_\_\_ Check Number 251 Amount 500.00

# NEVADA STATE BOARD OF PHARMACY

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

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

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

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New MDEG ☒ Ownership Change ☐ Name Change ☐ Location Change ☐

### FACILITY INFORMATION

Facility Name: National Seating + Mobility, Inc.

Physical Address: 5320 Power Inn Rd. Ste E Sacramento CA 95820-6741  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: 5959 Shallawford Rd., Ste. 443

City: Chattanooga State: TN Zip Code: 37421-2245

Telephone Number: 423-756-2268 Fax Number: 423-266-9690

E-mail: kgrady@NSM-seating.com Website: WWW.NSM-seating.com

### 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: closed to to Sun: closed to to Holidays: closed to to

### FACILITY ADMINISTRATOR INFORMATION

Name: Dave Butcher

Address: 5320 Power Inn Rd., Ste E

City: Sacramento State: CA Zip Code: 95820-6741

### TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- |  |   |
|--|---|
| <input type="checkbox"/> Medical Gases             | <input checked="" type="checkbox"/> Assistive Equipment   |
| <input type="checkbox"/> Respiratory Equipment     | <input type="checkbox"/> Parenteral and Enteral Equipment |
| <input type="checkbox"/> Life-sustaining equipment | <input type="checkbox"/> Orthotics and Prosthesis         |
| <input type="checkbox"/> Diabetic Supplies         | Other: _____  |

Board Use Only

Received

**DEC 03 2009**

Check Number

902

Amount

500.00

52602  
603

M



# NEVADA STATE BOARD OF PHARMACY

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

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

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

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New MDEG ☒ Ownership Change ☐ Name Change ☐ Location Change ☐

### FACILITY INFORMATION

Facility Name: North Coast Medical Supply

Physical Address: 2544 Campbell Place Ste 150  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: \_\_\_\_\_

City: Carlsbad State: CA Zip Code: 92009

Telephone Number: 760-434-9887 Fax Number: 760-434-6280

E-mail: tim@northcoastmed.com Website: www.northcoastmed.com

### DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8:30 to 5:00 Tue: 8:30 to 5:00 Wed: 8:30 to 5:00 Thu: 8:30 to 5:00  
Fri: 8:30 to 5:00 Sat: closed Sun: closed Holidays: closed

### FACILITY ADMINISTRATOR INFORMATION

Name: Tim Gady

Address: 2544 Campbell Place Suite 150

City: Carlsbad State: CA Zip Code: 92009

### TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- |   |   |
|---|---|
| <input type="checkbox"/> Medical Gases                | <input type="checkbox"/> Assistive Equipment              |
| <input type="checkbox"/> Respiratory Equipment        | <input type="checkbox"/> Parenteral and Enteral Equipment |
| <input type="checkbox"/> Life-sustaining equipment    | <input type="checkbox"/> Orthotics and Prosthesis         |
| <input checked="" type="checkbox"/> Diabetic Supplies | Other: _____  |

#### Board Use Only

Received DEC 15 2009 Check Number 153 Amount 500.00

52654  
606

**NEVADA STATE BOARD OF PHARMACY**  
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**APPLICATION FOR OUT-OF-STATE MDEG PROVIDER**  
**CORPORATION**

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

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New MDEG X Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_

**FACILITY INFORMATION**

Facility Name: PharMerica

Physical Address: 1100 Wilson Way, Suite 500, Smyrna, GA 30082-7218

(This must be a business address, we can not issue a license to a home address)

Mailing Address: 1100 Wilson Way, Suite 500

City: Smyrna State: GA Zip Code: 30082-7218

Telephone Number: 770/432-1621 Fax Number: 800/722-3599

E-mail: n/a Website: www.pharmerica.com

**DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING**

Mon: 8am to 7pm Tue: 8am to 7pm Wed: 8am to 7pm Thu: 8am to 7pm

Fri: 8am to 7pm Sat: N/A to Sun: N/A to Holidays: N/ to

**FACILITY ADMINISTRATOR INFORMATION**

Name: David Willis

Address: 1100 Wilson Way, Suite 500

City: Smyrna State: GA Zip Code: 30082-7218

**TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)**

- |  |  |
|--|--|
| <input type="checkbox"/> Medical Gases             | <input type="checkbox"/> Assistive Equipment                         |
| <input type="checkbox"/> Respiratory Equipment     | <input checked="" type="checkbox"/> Parenteral and Enteral Equipment |
| <input type="checkbox"/> Life-sustaining equipment | <input type="checkbox"/> Orthotics and Prosthesis                    |
| <input type="checkbox"/> Diabetic Supplies         | Other: _____   |

**Board Use Only**

Received DEC 10 2009 Check Number 935 Amount 500.00

52647  
605

**NEVADA STATE BOARD OF PHARMACY**  
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**APPLICATION FOR OUT-OF-STATE MDEG PROVIDER**  
**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 MDEG ☒ Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_

**FACILITY INFORMATION**

Facility Name: Sanvita CBGM, LLC

Physical Address: 205 Burlington Road Bedford, MA 01730  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: 200 Prospect Street

City: Waltham State: MA Zip Code: 02454

Telephone Number: (781) 894-0800 Fax Number: (781) 891-9072

E-mail: srodriques@novabio.com Website: \_\_\_\_\_

**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: James Lanza

Address: 200 Prospect Street

City: Waltham State: MA Zip Code: 02454

**TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)**

- |   |   |
|---|---|
| <input type="checkbox"/> Medical Gases                | <input type="checkbox"/> Assistive Equipment              |
| <input type="checkbox"/> Respiratory Equipment        | <input type="checkbox"/> Parenteral and Enteral Equipment |
| <input type="checkbox"/> Life-sustaining equipment    | <input type="checkbox"/> Orthotics and Prosthesis         |
| <input checked="" type="checkbox"/> Diabetic Supplies | Other: _____  |

**Board Use Only**

Received \_\_\_\_\_ Check Number 6079 Amount 500.00

# NEVADA STATE BOARD OF PHARMACY

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

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

FEE: **\$300.00** (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 MDEG Provider ☐ Ownership Change ☐ Name Change ☒ Location Change ☐

### FACILITY INFORMATION

Facility Name: PRN Medical Services, LLC DBA- Symbius Medical, LLC

Physical Address: 2311 W. Utopia Rd

Mailing Address: \_\_\_\_\_

City: Phoenix State: AZ Zip Code: 85027

Telephone Number: (623) 780-8686 Fax Number: 623-780-1887

### DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8a to 5p Tue: 8a to 5p Wed: 8a to 5p Thu: 8a to 5p

Fri: 8a to 5p Sat: \_\_\_\_\_ to \_\_\_\_\_ Sun: \_\_\_\_\_ to \_\_\_\_\_ Holidays: \_\_\_\_\_ to \_\_\_\_\_

### FACILITY ADMINISTRATOR INFORMATION

Name: Dwight Knox

Address: 2311 W. Utopia Rd

City: Phoenix State: AZ Zip Code: 85027

Telephone Number: (623) 780-8686

### TYPE OF MDEG PRODUCTS THAT WILL BE PROVIDED (CHECK ALL APPLICABLE)

☐ Medical Gases ☒ 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 \_\_\_\_\_ Check Number 100 Amount 300.00

**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.

New Pharmacy X Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Costco Wholesale Corporation  
Physical Address: 215 Deininger Circle, Suite A Corona, CA 92880  
Mailing Address: Attn: Licensing, 999 Lake Drive  
City: Issaquah State: WA Zip Code: 98027  
Telephone Number: (866)443-0060 Fax Number: (866)443-0066  
Toll Free Number: (866)443-0060  
E-mail: D570P4M@costco.com Website: www.costco.com  
Managing Pharmacist: Jimmy Wong License Number: 48768

**Hours of Operation:**

Monday thru Friday 5 am 7 pm Saturday 9:30 am 2 pm  
Sunday closed am \_\_\_\_\_ pm 24 Hours \_\_\_\_\_

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- |  |  |
|--|--|
| <input type="checkbox"/> Retail                    | <input type="checkbox"/> Off-site Cognitive Services |
| <input type="checkbox"/> Hospital (# beds _____)   | <input type="checkbox"/> Parenteral                  |
| <input type="checkbox"/> Internet                  | <input type="checkbox"/> Parenteral (outpatient)     |
| <input type="checkbox"/> Nuclear                   | <input type="checkbox"/> Outpatient/Discharge        |
| <input checked="" type="checkbox"/> Out of State   | <input checked="" type="checkbox"/> Mail Service     |
| <input type="checkbox"/> Ambulatory Surgery Center | <input type="checkbox"/> Long Term Care              |

**Board Use Only**

Received: DEC 09 2009 Check Number: 356 Amount: 500.00

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1749

M

**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.

New Pharmacy ☒ Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Depot Drug

Physical Address: 1040 N 2200 W, Suite 200

Mailing Address: \_\_\_\_\_

City: Salt Lake City State: UT Zip Code: 84116

Telephone Number: 801-595-4364 Fax Number: 801-595-2064

Toll Free Number: 800-877-0618

E-mail: bry@uphealth.com Website: Depot Drug . Com

Managing Pharmacist: Ben Johnson License Number: UT148205-170

**Hours of Operation:**

Monday thru Friday 6:30 am 3:00 pm      Saturday \_\_\_\_\_ am \_\_\_\_\_ pm  
Sunday \_\_\_\_\_ am \_\_\_\_\_ pm      24 Hours \_\_\_\_\_

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- ☐ Retail
- ☐ Hospital (# beds \_\_\_\_\_)
- ☐ Internet
- ☐ Nuclear
- ☒ Out of State
- ☐ Ambulatory Surgery Center

- ☐ Off-site Cognitive Services
- ☐ Parenteral
- ☐ Parenteral (outpatient)
- ☐ Outpatient/Discharge
- ☒ Mail Service
- ☐ Long Term Care

**Board Use Only**

Received: DEC 09 2009 Check Number: 11-24-09 Amount: 500.00

52617  
1751

**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

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New Pharmacy ☒ Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Griff's Compounding Center, Inc  
Physical Address: 3210 AVENUE B Ste A  
Mailing Address: SAME  
City: Scottsbluff State: NE Zip Code: 69361  
Telephone Number: 308 635-9800 Fax Number: 308-635-9899  
Toll Free Number: 888-516-9888  
E-mail: CUSTOMMEDS4U@yahoo.com Website: griff'scompoundingcenter.com  
Managing Pharmacist: CLARK Theodore Griff, HbRP License Number: 9455

**Hours of Operation:**

Monday thru Friday 9:30am 5:30pm  
Sunday \_\_\_\_\_am \_\_\_\_\_pm

Saturday \_\_\_\_\_am \_\_\_\_\_pm  
24 Hours \_\_\_\_\_

**TYPE OF PHARMACY**

- ☒ Retail
- ☐ Hospital (# beds \_\_\_\_\_)
- ☐ Internet
- ☐ Nuclear
- ☒ Out of State
- ☐ Ambulatory Surgery Center

**SERVICES PROVIDED**

- ☐ Off-site Cognitive Services
- ☐ Parenteral
- ☐ Parenteral (outpatient)
- ☐ Outpatient/Discharge
- ☒ Mail Service
- ☐ Long Term Care

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 358 Amount: 500.00

**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

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New Pharmacy X Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: ESI Mail Pharmacy Services, Inc dba. Express Scripts, Inc

Physical Address: 4610 E. Cotton Center Blvd, Ste 105 Phoenix, AZ 85040

Mailing Address: 3001 S Priest Drive

City: Tempe State: AZ Zip Code: 85282

Telephone Number: 866-363-8667 Fax Number: 877-512-5977

Toll Free Number: 866-363-8667

E-mail: Dsadauskas@express-scripts.com Website: www.express-scripts.com

Managing Pharmacist: Diane Sadauskas License Number: S015883

**Hours of Operation:**

Monday thru Friday 630 am 500 pm Saturday \_\_\_\_\_ am \_\_\_\_\_ pm  
Sunday \_\_\_\_\_ am \_\_\_\_\_ pm 24 Hours \_\_\_\_\_

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- ☐ Retail
- ☐ Hospital (# beds \_\_\_\_\_)
- ☐ Internet
- ☐ Nuclear
- ☒ Out of State
- ☐ Ambulatory Surgery Center

- ☐ Off-site Cognitive Services
- ☐ Parenteral
- ☐ Parenteral (outpatient)
- ☐ Outpatient/Discharge
- ☒ Mail Service
- ☐ Long Term Care

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 681 Amount: 500.00

52554  
1740



**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.

New Pharmacy ☒ Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(To Nevada) (Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Lee Silsby Compounding Pharmacy

Physical Address: 3216 Silsby Road

Mailing Address: 3216 Silsby Road

City: Cleveland Heights State: Ohio Zip Code: 44118

Telephone Number: 216-321-4300 Fax Number: 216-321-4363

Toll Free Number: 800-918-8831

E-mail: info@lee-silsby.com Website: lee-silsby.com

Managing Pharmacist: Robert S Wright License Number: 03-1-12300

**Hours of Operation:**

Monday thru ~~Friday~~ <sup>THURSDAY</sup> 9 am 7 pm Saturday 10 am 2 pm  
~~FRIDAY~~ <sup>Sunday</sup> 9 am 6 pm 24 Hours CLOSED SUNDAY <sub>By Appointment</sub>

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Retail         | <input type="checkbox"/> Off-site Cognitive Services |
| <input type="checkbox"/> Hospital (# beds _____)   | <input type="checkbox"/> Parenteral                  |
| <input type="checkbox"/> Internet                  | <input type="checkbox"/> Parenteral (outpatient)     |
| <input type="checkbox"/> Nuclear                   | <input type="checkbox"/> Outpatient/Discharge        |
| <input checked="" type="checkbox"/> Out of State   | <input checked="" type="checkbox"/> Mail Service     |
| <input type="checkbox"/> Ambulatory Surgery Center | <input type="checkbox"/> Long Term Care              |

**Board Use Only**

Received: DEC 01 2009 Check Number: 545 Amount: 500.00

52555  
1741 ✓

**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.

New Pharmacy ☒ Ownership Change ☐ Name Change ☐ Location Change ☐  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Precision Pharmacy

Physical Address: 4000 Empire Dr. #200

Mailing Address: Same

City: Bakersfield State: CA Zip Code: 93309

Telephone Number: (661) 377-3333 Fax Number: (661) 377-3334

Toll Free Number: (877) 734-3338

E-mail: info@myprecisionpharmacy.com Website: www.myprecisionpharmacy.co

Managing Pharmacist: Patricia Waldrup-Helgren License Number: 42842  
CALIFORNIA

**Hours of Operation:**

Monday thru Friday 8:15 am 5:15 pm

Saturday      am      pm

Sunday      am      pm

24 Hours     

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- ☒ Retail
- ☐ Hospital (# beds     )
- ☐ Internet
- ☐ Nuclear
- ☒ Out of State
- ☐ Ambulatory Surgery Center

- ☐ Off-site Cognitive Services
- ☐ Parenteral
- ☐ Parenteral (outpatient)
- ☐ Outpatient/Discharge
- ☒ Mail Service
- ☐ Long Term Care

**Board Use Only**

Received: DEC 17 2009 Check Number: 230 Amount: 500.00

52674  
1761

**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.

New Pharmacy ☒

Ownership Change ☐ Name Change ☐

(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Preferred RX, LLC

Physical Address: 1221 Corporate Drive East

Mailing Address: SAME AS ABOVE

City: Arlington State: TX Zip: 76006

Telephone Number: (817) 922-2979 Fax Number: 800-951-0866

Toll Free Number: SAME E-mail address: \_\_\_\_\_

Managing Pharmacist: Mandy Jackson License Number: TX 39317

**Hours of Operation:** 24 HRS

Monday thru Friday \_\_\_\_\_ am \_\_\_\_\_ pm

Saturday \_\_\_\_\_ am \_\_\_\_\_ pm

Sunday \_\_\_\_\_ am \_\_\_\_\_ pm

24 Hours ☒

DEA#: BP9964695

NCPDP #: \_\_\_\_\_

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- ☐ Retail
- ☐ Hospital (# beds \_\_\_\_\_)
- ☐ Correctional (# inmates \_\_\_\_\_)
- ☐ Nuclear
- ☒ Out of State
- ☐ Internet

- ☐ Off-site Cognitive Services
- ☐ Parenteral
- ☐ Parenteral (outpatient)
- ☐ Outpatient/Discharge
- ☒ Mail Service
- ☐ Long Term Care

**Board Use Only**

Received NOV 24 2009 Check Number 208 Amount 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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 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 ☐ Location Change ☐  
(Please provide current license number if making changes: WH \_\_\_\_\_)

**GENERAL INFORMATION**

Facility Name: AIDAPAK SERVICES, LLC

Physical Address: 1721 NE 64TH AVE, SUITE 120

Mailing Address: 1721 NE 64TH AVE, SUITE 120

City: VANCOUVER State: WA Zip Code: 98661

Telephone Number: 360 448-2090 Fax Number: 360 567-0173

Toll Free Number: \_\_\_\_\_

E-mail: Mrudem@aidapak.com Website: \_\_\_\_\_

Facility Manager: MICHAEL RODEMAN

Professional qualifications and experience of facility manager: \_\_\_\_\_

BS ACCOUNTING, MBA WASHINGTON STATE, CERTIFIED MANAGEMENT ACCOUNTANT  
(NONACTIVE)

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☒ Hospitals ☐ Wholesalers  
☐ Other: \_\_\_\_\_

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices  
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs  
☒ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 136 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**APPLICATION FOR OUT-OF-STATE WHOLESALE 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 Wholesaler X Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH \_\_\_\_\_)

**GENERAL INFORMATION**

Facility Name: BioForm Medical, Inc.  
Physical Address: 4133 Courtney Rd, Ste 10  
Mailing Address: (Same)  
City: Franksville State: WI Zip Code: 53126  
Telephone Number: (262) 835-3300 Fax Number: (262) 835-3330  
Toll Free Number: (866) 862-1221 (Voicemail only)  
E-mail: N/A Website: www.bioform.com  
Facility Manager: Dean Erickson  
Professional qualifications and experience of facility manager: See Attachment 1

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies      ☐ Practitioners      ☐ Hospitals      ☒ Wholesalers  
☐ Other: \_\_\_\_\_

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices      ☐ Hypodermic Devices  
☐ Poisons or Chemicals      ☐ Veterinary Legend Drugs  
☐ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: DEC 15 2009 Check Number: 911 Amount: 500.00

PT  
10-K

52655  
948

**NEVADA STATE BOARD OF PHARMACY**  
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 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 \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH 00539 )

**GENERAL INFORMATION**

Facility Name: Butler Schein Animal Health Supply

Physical Address: 3820 Twin Creeks Drive Columbus, Ohio 43204

Mailing Address: PO Box 7153

City: Dublin State: OH Zip Code: 43017

Telephone Number: 614-659-1702 Fax Number: 614-659-1703

Toll Free Number: N/A

E-mail: kknox@butlerahs.com Website: accessbutler.com

Facility Manager: Jammie Pierce

Professional qualifications and experience of facility manager: See attached.

**Types of licensed outlets or authorized persons firm will serve:**

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers  
☒ Other: Licensed Veterinarians

**Type of Products to be handled or wholesaled by firm:**

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices  
☐ Poisons or Chemicals ☒ Veterinary Legend Drugs  
☒ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

Board Use Only

Received: DEC 09 2009 Check Number: 398 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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 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 \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH<sup>01379</sup> )

**GENERAL INFORMATION**

Facility Name: Butler Schein Animal Health Supply

Physical Address: 850 South 3600 West Suite G. Salt Lake City, UT 84104

Mailing Address: PO Box 7153

City: Dublin State: OH Zip Code: 43017

Telephone Number: 614-659-1702 Fax Number: 614-659-1703

Toll Free Number: N/A

E-mail: kknox@butlerahs.com Website: accessbutler.com

Facility Manager: Tom Gardiner

Professional qualifications and experience of facility manager: See attached.

**Types of licensed outlets or authorized persons firm will serve:**

- ☐ Pharmacies      ☐ Practitioners      ☐ Hospitals      ☐ Wholesalers  
☒ Other: Licensed Veterinarians

**Type of Products to be handled or wholesaled by firm:**

- ☒ Legend Pharmaceuticals, Supplies or Devices      ☐ Hypodermic Devices  
☐ Poisons or Chemicals      ☒ Veterinary Legend Drugs  
☐ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 397 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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 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** <sup>x</sup> \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH <sup>01380</sup> )

**GENERAL INFORMATION**

Facility Name: Butler Schein Animal Health Supply

Physical Address: 19905 SW 95th Ave Tualatin, OR 97062

Mailing Address: PO Box 7153

City: Dublin State: OH Zip Code: 43017

Telephone Number: 614-659-1702 Fax Number: 614-659-1703

Toll Free Number: N/A

E-mail: kknox@butlerahs.com Website: accessbutler.com

Facility Manager: Eric McGibbon

Professional qualifications and experience of facility manager: See attached.

**Types of licensed outlets or authorized persons firm will serve:**

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers  
☒ Other: Licensed Veterinarians

**Type of Products to be handled or wholesaled by firm:**

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices  
☐ Poisons or Chemicals ☒ Veterinary Legend Drugs  
☒ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: DEC 09 2009 Check Number: 396 Amount: 500.00



**NEVADA STATE BOARD OF PHARMACY**  
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 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 \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH 01105 )

**GENERAL INFORMATION**

Facility Name: Butler Schein Animal Health Supply

Physical Address: 7940 W. Doe Avenue Suite 400 Visalia, CA 93291

Mailing Address: PO Box 7153

City: Dublin State: OH Zip Code: 43017

Telephone Number: 614-659-1702 Fax Number: 614-659-1703

Toll Free Number: N/A

E-mail: kknox@butlerahs.com Website: accessbutler.com

Facility Manager: Stan Trimble

Professional qualifications and experience of facility manager: See attached.

**Types of licensed outlets or authorized persons firm will serve:**

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers  
☒ Other: Licensed Veterinarians

**Type of Products to be handled or wholesaled be firm:**

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices  
☐ Poisons or Chemicals ☒ Veterinary Legend Drugs  
☒ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: DEC 09 2009 Check Number: 395 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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 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 <input checked="" type="checkbox"/>	Ownership Change <input type="checkbox"/>	Name Change <input type="checkbox"/>	Location Change <input type="checkbox"/>
(Please provide current license number if making changes: WH _____)			

**GENERAL INFORMATION**

Facility Name: Cardinal Health

Physical Address: 27680 Avenue Mentry

Mailing Address: Same as above

City: Valencia State: CA Zip Code: 91355

Telephone Number: 661-295-6100 Fax Number: 661-294-8218

Toll Free Number: \_\_\_\_\_

E-mail: pamela.smaldone@cardinalhealth.com Website: \_\_\_\_\_

Facility Manager: Pamela Smaldone Rondini

Professional qualifications and experience of facility manager: SEE ATTACHED

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies      ☒ Practitioners      ☒ Hospitals      ☒ Wholesalers  
☐ Other: \_\_\_\_\_

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices      ☒ Hypodermic Devices  
☐ Poisons or Chemicals      ☒ Veterinary Legend Drugs  
☒ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: DEC 01 2008 Check Number: 764 Amount: 500.00

Page 1 - 2009

10-K

52556  
942

**NEVADA STATE BOARD OF PHARMACY**  
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 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 \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH \_\_\_\_\_)

**GENERAL INFORMATION**

Facility Name: DeRoyal Industries, Inc.

Physical Address: 1755 Hwy 33 South

Mailing Address: " "

City: New Tazewell State: TN Zip Code: 37825

Telephone Number: 865-362-6217 Fax Number: 865-362-3738

Toll Free Number: \_\_\_\_\_

E-mail: tsexton@deroyal.com Website: WWW.deroyal.com

Facility Manager: Eddie Crocket

Professional qualifications and experience of facility manager: worked in distribution for 25 years.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☒ Practitioners ☒ Hospitals ☐ Wholesalers  
☐ Other: \_\_\_\_\_

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices  
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs  
☐ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 105 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**APPLICATION FOR OUT-OF-STATE WHOLESALE 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 Wholesaler ☒ Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH \_\_\_\_\_)

**GENERAL INFORMATION**

Facility Name: Fresenius Medical Care North America

Physical Address: 549 Sand Sage Road NW

Mailing Address: Same

City: Los Lunas State: NM Zip Code: 87031

Telephone Number: 505-565-8450 Fax Number: 505-565-8430

Toll Free Number: \_\_\_\_\_

E-mail: \_\_\_\_\_ Website: fmena.com

Facility Manager: Craig Connolly

Professional qualifications and experience of facility manager: Please see attached.

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers  
☒ Other: Dialysis Clinics

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices  
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs  
☐ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 568 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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 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 \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH \_\_\_\_\_)

**GENERAL INFORMATION**

Facility Name: Glenwood-LLC

Physical Address: 111 Cedar Lane, Englewood, NJ 07631

Mailing Address: 111 Cedar Lane

City: Englewood State: New Jersey Zip Code: 07631

Telephone Number: (201) - 569 - 0050 Fax Number: (201) - 569 - 0250

Toll Free Number: (800) 542 - 0772

E-mail: cshachar@glenwood-llc.com Website: www.glenwood-llc.com

Facility Manager: Cynthia A. Shachar

Professional qualifications and experience of facility manager: See attached resume

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies      ☒ Practitioners      ☒ Hospitals      ☒ Wholesalers  
☐ Other: \_\_\_\_\_

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices      ☐ Hypodermic Devices  
☐ Poisons or Chemicals      ☐ Veterinary Legend Drugs  
☐ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: DEC 01 2009 Check Number: 7082 Amount: 500.00

52557  
941

**NEVADA STATE BOARD OF PHARMACY**  
431 W Plumb Lane • Reno, NV 89509 • (775) 850-1440  
**APPLICATION FOR OUT-OF-STATE WHOLESALE 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: Medicis Aesthetics, Inc., a wholly-owned subsidiary of Medicis Pharmaceutical Corporation

Physical Address: 7720 N. Dobson Rd., Scottsdale AZ 85256

Mailing Address: 7720 N. Dobson Rd.

City: Scottsdale State: AZ Zip Code: 85256

Telephone Number: 602-808-8800 Fax Number: 602-808-0822

E-mail: jespinoza@medicis.com

Facility Manager: Julie Espinoza

Professional qualifications and experience of facility manager: Ms. Espinoza has been employed as the Manager, Warehouse & Logistics at Medicis since June 2006, where she is responsible for updating SOPs, ensuring completion of training, scheduling cGMP audits, and taking corrective action.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies    ☒ Practitioners    ☐ Hospitals    ☒ Wholesalers  
☐ Other \_\_\_\_\_

Type of Products to be handled or wholesaled by firm

☒ Legend Pharmaceuticals, Supplies or Devices    ☐ Hypodermic Devices  
☐ Poisons or Chemicals    ☐ Veterinary Legend Drugs  
☐ Controlled Substances (include copy of DEA certificate)  
☐ Other \_\_\_\_\_

**Board Use Only**

Received \_\_\_\_\_ Check Number 204 Amount 500.00

10-K

**NEVADA STATE BOARD OF PHARMACY**  
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: Medicis, The Dermatology Company, a wholly-owned subsidiary of Medicis Pharmaceutical Corporation

Physical Address: 7720 N. Dobson Rd., Scottsdale AZ 85256

Mailing Address: 7720 N. Dobson Rd.

City: Scottsdale State: AZ Zip Code: 85256

Telephone Number: 602-808-8800 Fax Number: 602-808-0822

E-mail: jespinoza@medicis.com

Facility Manager: Julie Espinoza

Professional qualifications and experience of facility manager: Ms. Espinoza has been employed as the Manager, Warehouse & Logistics at Medicis since June 2006, where she is responsible for updating SOPs, ensuring completion of training, scheduling cGMP audits, and taking corrective action.

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies    ☒ Practitioners    ☐ Hospitals    ☒ Wholesalers  
☐ Other \_\_\_\_\_

Type of Products to be handled or wholesaled by firm

☒ Legend Pharmaceuticals, Supplies or Devices    ☐ Hypodermic Devices  
☐ Poisons or Chemicals    ☐ Veterinary Legend Drugs  
☐ Controlled Substances (include copy of DEA certificate)  
☒ Other Over-the-Counter Pharmaceuticals

**Board Use Only**

Received \_\_\_\_\_ Check Number 205 Amount 500.00

10-K

**NEVADA STATE BOARD OF PHARMACY**  
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 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 X Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH \_\_\_\_\_)

**GENERAL INFORMATION**

Facility Name: OWENS & minor Healthcare Logistics

Physical Address: 6201 Global Distribution Way, Suite 101

Mailing Address: 6201 Global Distribution Way, Suite 101

City: LOUISVILLE State: KY Zip Code: 40228

Telephone Number: (502)-611-7550 Fax Number: (502)491-3955

Toll Free Number: \_\_\_\_\_

E-mail: Dwayne.Calk@owens-minor.com Website: www.omhcl.com

Facility Manager: Michael Dedman

Professional qualifications and experience of facility manager: <see attached>

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies      ☒ Practitioners      ☒ Hospitals      ☒ Wholesalers  
☐ Other: \_\_\_\_\_

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices      ☐ Hypodermic Devices  
☐ Poisons or Chemicals      ☐ Veterinary Legend Drugs  
☐ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: DEC 9 2009 Check Number: 535 Amount: 500.00

VAWD

52614  
945



**NEVADA STATE BOARD OF PHARMACY**  
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 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 \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: WH \_\_\_\_\_)

**GENERAL INFORMATION**

Facility Name: Physicians' Pharmaceutical Corporation  
Physical Address: 1050 Oak Ridge Turnpike Oak Ridge, TN 37831  
Mailing Address: 8930 Cross Park Drive, Suite 3  
City: Knoxville State: TN Zip Code: 37923  
Telephone Number: 865-692-5066 Fax Number: 865-692-6725  
Toll Free Number: \_\_\_\_\_  
E-mail: smassey@ppcdrx.com Website: www.ppcdrx.com  
Facility Manager: Ashley Morgan  
Professional qualifications and experience of facility manager: CPht,

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☒ Practitioners ☐ Hospitals ☐ Wholesalers  
☐ Other: \_\_\_\_\_

Type of Products to be handled or wholesaled by firm:

☐ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices  
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs  
☒ Controlled Substances (include copy of DEA)  
☐ Other: \_\_\_\_\_

**Board Use Only**

Received: DEC 14 2009 Check Number: 108 Amount: 500.00

52652  
946

**NEVADA STATE BOARD OF PHARMACY**  
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 <input type="checkbox"/>	Ownership Change <input checked="" type="checkbox"/> Name Change <input checked="" type="checkbox"/> (Please provide current license number if making changes: WH 01070)	See Attachment A
---	---	------------------

**FACILITY INFORMATION**

Facility Name: Promotech Logistics Solutions, LLC d/b/a PROMOTECH

Physical Address: 25 Madison Road

Mailing Address: Same as Above

City: Totowa State: NJ Zip Code: 07512

Telephone Number: 973-646-7500 Fax Number: 973-646-7579

E-mail: jporod@promotechdirect.com

Facility Manager: John Porod

Professional qualifications and experience of facility manager: \_\_\_\_\_

8 years pharmaceutical facility logistics

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies    ☒ Practitioners    ☐ Hospitals    ☐ Wholesalers  
☐ Other \_\_\_\_\_

Type of Products to be handled or wholesaled by firm

☒ Legend Pharmaceuticals, Supplies or Devices    ☒ Hypodermic Devices  
☒ Poisons or Chemicals    ☒ Veterinary Legend Drugs  
☒ Controlled Substances (include copy of DEA certificate) See Attachment E  
☐ Other OTC Drugs, Cosmetics, Plasma

**Board Use Only**

Received NOV 25 2009 Check Number 825 Amount 500.00

*10-K report*

**NEVADA STATE BOARD OF PHARMACY**  
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: Ucyclyd Pharma, Inc., a wholly-owned subsidiary of Medicis Pharmaceutical Corporation

Physical Address: 7720 N. Dobson Rd., Scottsdale AZ 85256

Mailing Address: 7720 N. Dobson Rd.

City: Scottsdale State: AZ Zip Code: 85256

Telephone Number: 602-808-8800 Fax Number: 602-808-0822

E-mail: jespinoza@medicis.com

Facility Manager: Julie Espinoza

Professional qualifications and experience of facility manager: Ms. Espinoza has been employed as the Manager, Warehouse & Logistics at Medicis since June 2006, where she is responsible for updating SOPs, ensuring completion of training, scheduling cGMP audits, and taking corrective action.

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies    ☒ Practitioners    ☒ Hospitals    ☒ Wholesalers  
☐ Other \_\_\_\_\_

Type of Products to be handled or wholesaled by firm

☒ Legend Pharmaceuticals, Supplies or Devices    ☐ Hypodermic Devices  
☐ Poisons or Chemicals    ☐ Veterinary Legend Drugs  
☐ Controlled Substances (include copy of DEA certificate)  
☐ Other \_\_\_\_\_

**Board Use Only**

Received \_\_\_\_\_ Check Number 203 Amount 500.00

10-K

**APPLICATION FOR NEVADA MDEG PROVIDER  
NON PUBLICLY TRADED 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 MDEG ☒ Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
Please provide current license number if making changes: \_\_\_\_\_

**FACILITY INFORMATION**

Facility Name: Hathaway Medical

Physical Address: 6053 S. Fort Apache Rd. LV, NV 89148  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: 4117 California Condor

City: North Las Vegas State: NV Zip Code: 89084

Telephone Number: 702 526 1710 Fax Number: 702 387 1710

E-mail: hathawaymedical@yahoo.com Website: N/A

**DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING**

Mon: NA to \_\_\_\_\_ Tue: \_\_\_\_\_ to \_\_\_\_\_ Wed: \_\_\_\_\_ to \_\_\_\_\_ Thu: \_\_\_\_\_ to \_\_\_\_\_  
Fri: \_\_\_\_\_ to \_\_\_\_\_ Sat: \_\_\_\_\_ to \_\_\_\_\_ Sun: \_\_\_\_\_ to \_\_\_\_\_ Holidays: \_\_\_\_\_ to \_\_\_\_\_

*doesn't see  
patients in  
office -*

**FACILITY ADMINISTRATOR INFORMATION**

Name: Michael Hathaway

Address: 4117 California Condor

City: North Las Vegas State: NV Zip Code: 89084

**TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)**

- ☐ Medical Gases
- ☐ Respiratory Equipment
- ☐ Life-sustaining equipment
- ☐ Diabetic Supplies

- ☐ Assistive Equipment
- ☐ Parenteral and Enteral Equipment
- ☐ Orthotics and Prosthesis

Other: Bone Growth Stimulators

**Board Use Only**

Received \_\_\_\_\_ Check Number 4068 Amount 500.00

# NEVADA STATE BOARD OF PHARMACY

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

## APPLICATION FOR NEVADA MDEG PROVIDER

### NON PUBLICLY TRADED 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 MDEG X Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
Please provide current license number if making changes: \_\_\_\_\_

#### FACILITY INFORMATION

Facility Name: TRUE Pharmacy

Physical Address: 1100 N Martin Lutherking Blvd Suite E Las Vegas NV  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: 1100 N Martin Lutherking Blvd Suite E

City: Las Vegas State: NV Zip Code: 89106

Telephone Number: 702-474-1100 Fax Number: 702-647-0200

E-mail: N/A Website: N/A

#### DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9am to 6pm Tue: 9am to 6pm Wed: 9am to 6pm Thu: 9am to 6pm

Fri: 9am to 6pm Sat: 8am to 3pm Sun: closed Holidays: closed to closed

#### FACILITY ADMINISTRATOR INFORMATION

Name: Daniel G Eshetie

Address: 104 Summit Creek Ave

City: Las Vegas State: NV Zip Code: 89031

#### TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☒ Medical Gases

☒ Respiratory Equipment

☐ Life-sustaining equipment

☒ Diabetic Supplies

☒ Assistive Equipment

☒ Parenteral and Enteral Equipment

☒ Orthotics and Prosthesis

Other: wheel chairs, scooters

Board Use Only

Received

DEC 09 2009

Check Number

331

Amount

500.00

52618  
604

# NEVADA STATE BOARD OF PHARMACY

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

## APPLICATION FOR NEVADA MDEG PROVIDER

### NON PUBLICLY TRADED 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 MDEG ☒ Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
Please provide current license number if making changes: \_\_\_\_\_

### FACILITY INFORMATION

Facility Name: Zee Medical Service Company

Physical Address: 1618 W. Oakley Blvd, Las Vegas NV 89102  
(This must be a business address, we can not issue a license to a home address)

Mailing Address: 1618 W. Oakley Blvd,

City: Las Vegas State: NV Zip Code: 89102

Telephone Number: 702-384-3507 Fax Number: 702-382-8037

E-mail: ZeeLV@earthlinkmail.com Website: zee-medical.com

### DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 7 to 4 Tue: 7 to 4 Wed: 7 to 4 Thu: 7 to 4

Fri: 7 to 4 Sat: \_\_\_\_\_ to \_\_\_\_\_ Sun: \_\_\_\_\_ to \_\_\_\_\_ Holidays: \_\_\_\_\_ to \_\_\_\_\_

### FACILITY ADMINISTRATOR INFORMATION

Name: Kenneth A. Skelton

Address: 10917 Grand Cypress Ave

City: Las Vegas State: NV Zip Code: 89134

### TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

- |  |   |
|--|---|
| <input type="checkbox"/> Medical Gases             | <input type="checkbox"/> Assistive Equipment              |
| <input type="checkbox"/> Respiratory Equipment     | <input type="checkbox"/> Parenteral and Enteral Equipment |
| <input type="checkbox"/> Life-sustaining equipment | <input type="checkbox"/> Orthotics and Prosthesis         |
| <input type="checkbox"/> Diabetic Supplies         | Other: <u>AED</u>   |

### Board Use Only

Received \_\_\_\_\_ Check Number 942 Amount 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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

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 ☐ Location Change ☐  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: BHS SPECIALTY PHARMACY  
Physical Address: 2870 S. MARYLAND PKWY, LAS VEGAS, NV 89109  
Mailing Address: 2644 HOURGLASS DR  
City: HENDERSON State: NV Zip Code: 89052  
Telephone Number: (702) 290-4613 Fax Number: (702) 433-4846  
Toll Free Number: \_\_\_\_\_  
E-mail: BHS PHARMACY@Gmail.com Website: WWW.BHS PHARMACY.COM (NE No Pla Met)  
Managing Pharmacist: RACHEL KEMISOLA License Number: 15199  
TUNRAREBI

**Hours of Operation:**

Monday thru Friday 8 am 5 pm Saturday \_\_\_\_\_ am \_\_\_\_\_ pm  
Sunday \_\_\_\_\_ am \_\_\_\_\_ pm 24 Hours \_\_\_\_\_

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Retail         | <input type="checkbox"/> Off-site Cognitive Services |
| <input type="checkbox"/> Hospital (# beds _____)   | <input type="checkbox"/> Parenteral                  |
| <input checked="" type="checkbox"/> Internet       | <input type="checkbox"/> Parenteral (outpatient)     |
| <input type="checkbox"/> Nuclear                   | <input type="checkbox"/> Outpatient/Discharge        |
| <input type="checkbox"/> Out of State              | <input checked="" type="checkbox"/> Mail Service     |
| <input type="checkbox"/> Ambulatory Surgery Center | <input type="checkbox"/> Long Term Care              |

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 318 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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

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 X Ownership Change \_\_\_\_\_ Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: HORIZON SURGICAL CENTER

Physical Address: 10561 JEFFREYS ST.

Mailing Address: 10561 JEFFREYS ST.

City: HENDERSON State: NV Zip: 89052

Telephone Number: 702-370-7149 Fax Number: PENDING

Toll Free Number: N/A E-mail: CF@NSAMC-11C.COM

Managing Pharmacist: MARY GREAR RPH License Number: 10687

**Hours of Operation:**

Monday thru Friday 6<sup>30</sup> am 5<sup>30</sup> pm Saturday Closed am — pm

Sunday Closed am — pm 24 Hours —

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- |  |  |
|--|--|
| <input type="checkbox"/> Retail                              | <input type="checkbox"/> Off-site Cognitive Services |
| <input type="checkbox"/> Hospital (# beds <u>  </u> )        | <input type="checkbox"/> Parenteral                  |
| <input type="checkbox"/> Correctional (# inmates <u>  </u> ) | <input type="checkbox"/> Parenteral (outpatient)     |
| <input type="checkbox"/> Nuclear                             | <input type="checkbox"/> Outpatient/Discharge        |
| <input type="checkbox"/> Out of State                        | <input type="checkbox"/> Mail Service                |
| <input checked="" type="checkbox"/> ASC                      | <input type="checkbox"/> Long Term Care              |
| <input type="checkbox"/> Internet                            | <input checked="" type="checkbox"/> Surgery Center   |

**Board Use Only**

Received \_\_\_\_\_ Check Number 991 Amount 500.00



**NEVADA STATE BOARD OF PHARMACY**  
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

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 ☐ Location Change ☐  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Metro Drugs  
Physical Address: 6338 W. Sahara Las Vegas, NV 89146  
Mailing Address: 9341 Buckhaven DR  
City: Las Vegas State: NV Zip Code: 89117  
Telephone Number: 702 448 3810 Fax Number: 702 448 3810  
Toll Free Number: \_\_\_\_\_  
E-mail: Curphu@aol.com Website: \_\_\_\_\_  
Managing Pharmacist: Joseph Salazar License Number: 11157

**Hours of Operation:**

Monday thru Friday 8 am 6 pm                      Saturday 8 am 6 pm  
Sunday 10 am 3 pm                                      24 Hours \_\_\_\_\_

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Retail         | <input type="checkbox"/> Off-site Cognitive Services |
| <input type="checkbox"/> Hospital (# beds _____)   | <input type="checkbox"/> Parenteral                  |
| <input type="checkbox"/> Internet                  | <input type="checkbox"/> Parenteral (outpatient)     |
| <input type="checkbox"/> Nuclear                   | <input type="checkbox"/> Outpatient/Discharge        |
| <input type="checkbox"/> Out of State              | <input checked="" type="checkbox"/> Mail Service     |
| <input type="checkbox"/> Ambulatory Surgery Center | <input type="checkbox"/> Long Term Care              |

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 1009 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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

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 X Name Change \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH 01713)

**GENERAL INFORMATION**

Pharmacy Name: Nevada Drug Compounding Pharmacy East

Physical Address: 3041 W. Horizon Ridge Pkwy. #100

Mailing Address: 3041 W. Horizon Ridge Pkwy. #100

City: Henderson State: NV Zip Code: 89052

Telephone Number: (702)293-6900 Fax Number: \_\_\_\_\_

Toll Free Number: N/A

E-mail: nevadadrug@aol.com Website: N/A

Managing Pharmacist: Scott Ricci License Number: 11997  
*see attached*

**Hours of Operation:**

Monday thru Friday 9 am 5:30 pm Saturday - am - pm  
Sunday - am - pm 24 Hours -

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- ☒ Retail
- ☐ Hospital (# beds \_\_\_\_\_)
- ☐ Internet
- ☐ Nuclear
- ☐ Out of State
- ☐ Ambulatory Surgery Center

- ☐ Off-site Cognitive Services
- ☐ Parenteral
- ☒ Parenteral (outpatient)
- ☐ Outpatient/Discharge
- ☐ Mail Service
- ☐ Long Term Care

**Board Use Only**

Received: NOV 17 2009 Check Number: 428 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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

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 \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Nevada Drug Compounding Pharmacy West

Physical Address: 6350 W. Flamingo Blvd., Suite 1

Mailing Address: 6350 W. Flamingo Blvd., Suite 1

City: Las Vegas State: NV Zip Code: 89103

Telephone Number: (702)564-2079 Fax Number: (702)564-8273

Toll Free Number: N/A

E-mail: N/A Website: N/A

Managing Pharmacist: Doug Camman License Number: 13340

**Hours of Operation:**

Monday thru Friday 9 am 5:30 pm

Saturday - am - pm

Sunday - am - pm

24 Hours -

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- ☒ Retail
- ☐ Hospital (# beds \_\_\_\_\_)
- ☐ Internet
- ☐ Nuclear
- ☐ Out of State
- ☐ Ambulatory Surgery Center

- ☐ Off-site Cognitive Services
- ☐ Parenteral
- ☒ Parenteral (outpatient)
- ☐ Outpatient/Discharge
- ☐ Mail Service
- ☐ Long Term Care

**Board Use Only**

Received: NOV 17 2009 Check Number: 427 Amount: 500.00

52398  
1723

**NEVADA STATE BOARD OF PHARMACY**  
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

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 X Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH01518)

**GENERAL INFORMATION**

Pharmacy Name: REMEDY RX (FORMERLY APPLIED PHARMACEUTICAL SERVICES)  
Physical Address: 5785 S. FORT APACHE RD STE A LV NV 89148  
Mailing Address: 5785 S. FORT APACHE RD STE A LV NV 89148  
City: LAS VEGAS State: NV Zip Code: 89148  
Telephone Number: 304-0770 Fax Number: 304-0778  
Toll Free Number: 800-300-7131  
E-mail: appliedrx@aol.com Website: appliedrx.com  
Managing Pharmacist: TIMOTHY A LOPEZ License Number: NV 13312

**Hours of Operation:**

Monday thru Friday 9 am 5 pm      Saturday \_\_\_\_\_ am \_\_\_\_\_ pm  
Sunday \_\_\_\_\_ am \_\_\_\_\_ pm      24 Hours \_\_\_\_\_

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Retail         | <input type="checkbox"/> Off-site Cognitive Services |
| <input type="checkbox"/> Hospital (# beds _____)   | <input checked="" type="checkbox"/> Parenteral       |
| <input type="checkbox"/> Internet                  | <input type="checkbox"/> Parenteral (outpatient)     |
| <input type="checkbox"/> Nuclear                   | <input type="checkbox"/> Outpatient/Discharge        |
| <input type="checkbox"/> Out of State              | <input type="checkbox"/> Mail Service                |
| <input type="checkbox"/> Ambulatory Surgery Center | <input type="checkbox"/> Long Term Care              |

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 724 Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440  
**APPLICATION FOR NEVADA PHARMACY LICENSE**  
**SOLE PROPRIETORSHIP**

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 \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Smoke Ranch Surgery Center  
Physical Address: 7180 Smoke Ranch Road Las Vegas NV 89128  
Mailing Address: same  
City: Las Vegas State: NV Zip Code: 89128  
Telephone Number: (702) 483-2270 Fax Number: (702) 851-3278  
Toll Free Number: N/A  
E-mail: mtaylor@nvapineclinic.com Website: N/A  
Managing Pharmacist: Doug Cumman License Number: 13340

**Hours of Operation:**

Monday thru Friday 8 am 5 pm      Saturday 8 am 3 pm  
Sunday N/A am N/A pm      24 Hours N/A

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- ☐ Retail
- ☐ Hospital (# beds \_\_\_\_\_)
- ☐ Internet
- ☐ Nuclear
- ☐ Out of State
- ☒ Ambulatory Surgery Center

- ☐ Off-site Cognitive Services
- ☐ Parenteral
- ☐ Parenteral (outpatient)
- ☐ Outpatient/Discharge
- ☐ Mail Service
- ☐ Long Term Care

**Board Use Only**

Received: \_\_\_\_\_ Check Number: mo Amount: 500.00

**NEVADA STATE BOARD OF PHARMACY**  
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

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 \_\_\_\_\_ Location Change \_\_\_\_\_  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: TRUE PHARMACY

Physical Address: 1100 N MARTIN LUTHER KING BLVD SUITE E

Mailing Address: 1100 N MARTIN LUTHER KING BLVD SUITE E

City: LAS VEGAS State: NV Zip Code: 89106

Telephone Number: 702-474-1100 Fax Number: 702-647-0200

Toll Free Number: N/A

E-mail: N/A Website: N/A

Managing Pharmacist: DANIEL G ESKETIE License Number: 16860

**Hours of Operation:**

Monday thru Friday 9 am 6 pm Saturday 8 am 3 pm  
Sunday Closed am Closed pm 24 Hours N/A

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Retail         | <input type="checkbox"/> Off-site Cognitive Services |
| <input type="checkbox"/> Hospital (# beds _____)   | <input type="checkbox"/> Parenteral                  |
| <input type="checkbox"/> Internet                  | <input type="checkbox"/> Parenteral (outpatient)     |
| <input type="checkbox"/> Nuclear                   | <input type="checkbox"/> Outpatient/Discharge        |
| <input type="checkbox"/> Out of State              | <input type="checkbox"/> Mail Service                |
| <input type="checkbox"/> Ambulatory Surgery Center | <input type="checkbox"/> Long Term Care              |

**Board Use Only**

Received: DEC 09 2009 Check Number: 330 Amount: 500.00

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**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**Case No. 09-040-RPH-S**

**Case No. 09-040-PH-S**

**v.**

**WARREN C. ROLAN, R.Ph.,  
Certificate of Registration No: #15406**

**MOUNTAIN VIEW PHARMACY,  
Certificate of Registration No. PH01993**

**Respondent.**

---

**RESPONDENTS' JOINT MOTION FOR DISCOVERY, FOR ISSUANCE OF  
SUBPOENAS, AND FOR CONTINUANCE OF HEARING SCHEDULED FOR JANUARY  
14, 2010**

Comes Now, Respondents Warren C. Rolan, R.Ph., and Mountain View Pharmacy, by and through their undersigned counsel of record, Richard A. Schonfeld, Esq., of the law offices of Chesnoff & Schonfeld, and John V. Spilotro, Esq., and hereby Moves for Discovery, for Issuance of Subpoenas, and for a Continuance of the January 14, 2010, hearing.

This Motion is made and based upon the papers and pleadings on file herein, the attached

///



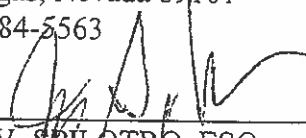
Memorandum of Points and Authorities, and any argument that may be heard.

DATED this 28<sup>th</sup> day of December, 2009.

RESPECTFULLY SUBMITTED:



RICHARD A. SCHONFELD, ESQ.  
Nevada Bar No. 6815  
520 South Fourth Street  
Las Vegas, Nevada 89101  
(702) 384-5563



JOHN V. SPILOTRO, ESQ.  
Nevada Bar No. 4134  
626 South Sixth Street  
Las Vegas, Nevada 89101

**MEMORANDUM OF POINTS AND AUTHORITIES**

Pursuant to NRS 639.2485 the Board is to authorize the issuance of Subpoenas for discovery purposes in these proceedings.

Pursuant to NRS 622A.330 the Respondents are entitled to all evidence that may be presented to the Board in support of the allegations against Respondents.

Additionally, pursuant to NRS 622A.330 the Respondents are entitled to receive a list of proposed witnesses that will be presented against them.

In light of the foregoing, the Respondents request all evidence that may be used against them, a list of witnesses that will be presented against them, and issuance of the following subpoenas:

1. Duces Tecum for all medical records related to Claudia Cannon and/or the patient referenced in the Notice of Intended Action and Accusation that allegedly died at Passavant Area Hospital in Jacksonville, Illinois, from August 18, 2008 through May 15, 2009.

The basis for this request is in order to respond to the Second Cause of Action in the Complaint wherein it is alleged that Respondent did not confirm that a physical examination had occurred within the last six months before the prescription was allegedly written by Respondent Rolan. These records are required to demonstrate that Claudia Cannon had in fact been physically examined within six months prior to the alleged prescriptions.

2. Subpoena Duces Tecum to Yashwant Amin, for all records in the possession of the Illinois Department of Financial and Professional Regulation related to Claudia Cannon;

3. Subpoena Duces Tecum to Dr. Gloria C. Fong for all records related to Claudia Cannon;

4. Subpoena Duces Tecum to Dr. Charles Myers for all records related to Claudia Cannon;

5. Subpoena Duces Tecum to Dr. Jack Edward Pickering for all records related to Claudia

Cannon;

6. Subpoena Duces Tecum to the Morgan County Coroner for the autopsy and toxicology report related to the death of Claudia Cannon;

7. Subpoena Duces Tecum to Federal Bureau of Investigations Agent John Buma for all FBI 302 reports, or other reports, related to the death of Claudia Cannon;

8. Subpoena Duces Tecum to Federal Bureau of Investigations Agent John Buma for all FBI 302 reports, or other reports, related to Warren Rolan and/or Mountain View Pharmacy;

9. Subpoena Duces Tecum to Pharmakind for all records related to Claudia Cannon;

10. Subpoena Duces Tecum to Alliance Health Group for all records related to Claudia Cannon;

#### MOTION FOR CONTINUANCE

Pursuant to NAC 639.120 the Respondents are requesting a continuance of the hearing so that they can conduct discovery, can receive evidence that is intended to be used against them at the Board proceedings, and so they can adequately defend themselves herein.

Nevada law is clear that a Respondent to an administrative proceeding is guaranteed due process. *Bivins Construction v. State Contractors' Board*, 107 Nev. 281, 283. The Respondent is entitled to notice of the issues on which decisions will turn and the factual material on which the agency relies for decision so that he may rebut it. *Bowman Transportation v. Ark.-Best Freight System*, 419 U.S. 281, 288-89.

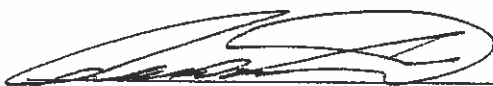
The Board commenced its investigation in May of 2009, and proposes to provide Respondent with approximately thirty days within which to formulate its defense. If the hearing is not continued to afford the Respondent adequate time to receive and review the evidence in possession of the board, issue subpoenas, file Motions, and prepare their defense, the Respondents'

1  
2 due process rights will be violated.

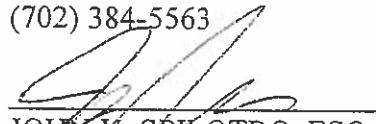
3 For the foregoing reasons it is respectfully requested that the Board issue the above stated  
4 Subpoenas, require production of discovery and a list of witnesses, and continue the hearing  
5 scheduled for January 14, 2010.

6 DATED this 28<sup>th</sup> day of December, 2009.  
7  
8

9 RESPECTFULLY SUBMITTED:

10  
11 

12 RICHARD A. SCHONFELD, ESQ.  
13 Nevada Bar No. 6815  
14 520 South Fourth Street  
15 Las Vegas, Nevada 89101  
16 (702) 384-5563

17   
18 JOHN V. SPILOTRO, ESQ.  
19 Nevada Bar No. 4134  
20 626 South Sixth Street  
21 Las Vegas, Nevada 89101  
22  
23  
24  
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28



**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**v.**

**NOTICE OF INTENDED ACTION  
AND ACCUSATION**

**WARREN C. ROLAN, R.Ph.,  
Certificate of Registration No: #15406,**

**Case No. 09-040-RPH-S**

**MOUNTAIN VIEW PHARMACY,  
Certificate of Registration No: PH01993,**

**Case No. 09-040-PH-S**

**Respondents.**

\_\_\_\_\_/

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.

I.

The Nevada State Board of Pharmacy has jurisdiction over this matter because Respondent Warren C. Rolan is a pharmacist licensed by the Board and Respondent Mountain View Pharmacy (Mountain View) is a pharmacy licensed by the Board located at 3150 North Tenaya Way #170, Las Vegas, Nevada.

II.

On May 26, 2009, the Board received a letter and supporting documentation from Yashwant Amin, RPh, PhD., Director of Drug Compliance for the Illinois Department of Financial and Professional Regulation notifying the Board that a patient had died at Passavant Area Hospital in Jacksonville, Illinois after purchasing and

consuming drugs from the internet. The letter was sent to inform the Board that a pharmacy in Nevada might have been involved in the sale and dispensing of medications to the deceased patient. The complaint also detailed the death of the Illinois patient and was accompanied with a list of medications that were recovered from the decedent's residence.

### III.

The list detailed the pharmacy name, pharmacy address, pharmacy phone number, prescribing physician, filling pharmacist's initials, date filled, and comments. All medications on the list were either carisoprodol 350mg. #180 or Tramadol 50mg. #180. The list identified Mountain View Pharmacy, located at 3150 North Tenaya Way, Suite 170 in Las Vegas, Nevada 89128 with the telephone number (866) 465-0791, as having filled three prescriptions for carisoprodol 350mg. #180 for the deceased patient. The list showed that the first prescription was filled by Mountain View on February 19, 2009 with the filling pharmacists initials of RK prescribed by Dr. Gloria C. Fong with the comment "different 1<sup>st</sup> name on script;" the second on April 10, 2009 with the filling pharmacists initials of RK prescribed by Dr. Charles Myers; and the third on March 26, 2009 with the pharmacists initials of RK prescribed by Dr. Jack Edward Pickering. Neither Dr. Fong, Dr. Myers, nor Dr. Pickering are physicians licensed in Nevada.

### IV.

Morgan County Coroner, Jeff Lair, identified the deceased patient as 59-year-old Claudia Cannon from Chapin, Illinois. Ms. Cannon's date of death was May 15, 2009. Ms. Cannon's death was ruled as accidental caused by Acute Liver Failure, Toxic Liver Damage and Chronic Ultracet (Tramadol) Abuse.

V.

Special Agent John Buma from the F.B.I. Springfield, Illinois office confirmed that a large number of prescription medication bottles were recovered from Claudia Cannon's residence and impounded by his office. Special Agent Buma confirmed that over 7,000 dosage units of carisoprodol 350 mg tablets or Tramadol 50mg tablets from prescriptions obtained through the internet from about seven different states were impounded. Special Agent Buma stated that three bottles of medications from Mountain View had been impounded on scene.

VI.

Warren Rolan, the Owner/Pharmacy Manager for Mountain View was contacted and identified four prescriptions that he filled for Claudia Cannon:

1. Order #85713 carisoprodol 350mg. #180 dated 2/19/09
2. Order #99817 Tramadol 50mg. #180 dated 3/13/09
3. Order #99808 Soma 350mg. #180 dated 3/36/09
4. Order #118102 Soma 350mg. #180 dated 4/10/09

VII.

On June 5, 2008, Warren Rolan received a fax from PHARMAKIND, a subsidiary of Alliance Health Group promoting an internet pharmacy business. Warren Rolan stated that he never signed up for the business but that prescriptions were sent to him online after the patient filled out an online questionnaire. Warren Rolan stated that the prescriptions were usually for carisoprodol (a CIV controlled substance) and Tramadol (a dangerous drug). The prescriptions had the physician's name, address, telephone number, license number and DEA number listed. Warren Rolan at first contacted some of the physicians telephonically to verify the authenticity of the prescriptions, but later



ceased this activity and filled the prescriptions without contacting the physicians. Warren Rolen stated that he would accept or reject the prescriptions and on the prescriptions that he would accept to fill later in the day, he would print labels, patient profiles, prescriptions and mailing labels at Mountain View. The prescriptions would then be filled and mailed using DHL initially and then later on Federal Express as the shipper. Warren Rolen kept the records for his internet business in boxes in a storage room inside the pharmacy in no chronological order. Additionally, the patient profiles for the internet pharmacy were only retrievable through the internet computer and only by specific prescription. Warren Rolen's internet prescription business and computer system was separate from Warren Rolen's Mountain View computer system. Warren Rolen never reported the filling of any internet pharmacy prescription to the Nevada Controlled Substance Task Force.

#### VIII.

Warren Rolen had the original downloaded prescriptions for three of the four prescriptions that he filled for Claudia Cannon via PHARMAKIND. The missing prescription, Order #118102 was for Soma, but there was a Federal Express delivery confirmation notice for the prescription that confirmed it had been sent to Claudia Cannon. Warren Rolen admitted that he had filled over 5000 prescriptions under the internet service PHARMAKIND and did not verify the authenticity of any doctor/patient relationship for any of Claudia Cannon's prescriptions.

#### IX.

Mountain View was not registered as an internet pharmacy and was not licensed in any other state as an out-of-state or internet pharmacy.

X.

Warren Rolan voluntarily submitted his Wells Fargo bank account records which show 42 deposits totaling \$117,000.00 from PHARMAKIND, from June 6, 2008 through May 21, 2009.

**FIRST CAUSE OF ACTION**

XI.

For acting as an internet pharmacy without appropriate licensure and or certification, Respondents Warren Rolan and Mountain View have violated NRS 453.3618 and/or NRS 453.3638(1) and/or NRS 639.210(4) and/or NRS 639.23288(1)(a) and/or NAC 639.426(1) and/or NAC 639.945(1)(k).

**SECOND CAUSE OF ACTION**

XII.

For failing to establish that a bona fide relationship existed between the Claudia Cannon and the doctors who wrote her prescriptions by confirming that a physical examination had occurred within the last six months before the prescription was written, Respondent Warren Rolan violated NRS 639.235 and/or 639.210(4) and/or NAC 639.945(1)(i).

**THIRD CAUSE OF ACTION**

XIII.

For failing to maintain prescription records in chronological order, Respondent Warren Rolan violated NRS 639.210(4) and/or NAC 639.706(1),(2) and (3) and/or NAC 639.945(1)(i).

#### **FOURTH CAUSE OF ACTION**

XIV.

For failing to report to the Nevada Controlled Substance Task Force the controlled substance prescriptions for Claudia Cannon and all of the other prescriptions filled for PHARMAKIND that were controlled substances, Respondents Warren Rolen and Mountain View have violated NRS 639.210(4) and/or NAC 639.926(1) and/or NAC 639.945(1)(i).

#### **FIFTH CAUSE OF ACTION**

XV.

For failing to provide a toll-free telephone number to provide telephonic counseling for patients being served out-of-state, Respondents Warren Rolen and Mountain View have violated NRS 639.210(4) and/or NAC 639.708(4)(a) and/or NAC 639.945(1)(i).

#### **SIXTH CAUSE OF ACTION**

XVI.

For failing to provide written patient information as provided for in NAC 639.707(1) and (2) and failing to review patient records regarding overutilization of the drug and drug abuse which contributed to the death of Claudia Cannon, Respondent Warren Rolen, violated NRS 639.210(4) and/or NAC 639.707(3) and (4) and/or NAC 639.945(1)(i).

#### **SEVENTH CAUSE OF ACTION**

XVI.

In participating in a course of action intended to assist in the fraudulent and deceitful purchasing of medications, including controlled substances, via the

internet with knowledge that, or under circumstances that Respondents Warren Rolan and Mountain View should have reasonably known that the sale of the medications were unlawful, questionable, or illegal, Respondents Warren Rolan and Mountain View violated NRS 639.210(4) and/or (12) and NAC 639.945(1)(h), and (i). Pursuant to NAC 639.955(7), all four orders that were filled and sent to Claudia Cannon by Respondents are grouped in this cause of action for the Board's administrative convenience, but the Board may impose separate discipline for each of the four orders.

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 10<sup>th</sup> day of December, 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,**

**v.**

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

**WARREN C. ROLAN, RPH  
Certificate of Registration No. 15406**

**Case No. 09-040-RPH-S**

**Respondent.**

\_\_\_\_\_/

**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.

**II.**

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. 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.


III.

The Board has reserved Wednesday, January 13, 2010 as the date for a hearing on this matter at the Las Vegas Chamber of Commerce, 6671 Las Vegas Boulevard South, Las Vegas, 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 30<sup>th</sup> day of December, 2009.

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

**ORIGINAL**

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**v.**

**Petitioner,**

**ANSWER AND NOTICE  
OF DEFENSE**

**WARREN C. ROLAN, RPH  
Certificate of Registration No. 15406**

**Case No. 09-040-RPH-S**

**Respondent.**

\_\_\_\_\_/

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").

"See Attached"

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

"See Attached"

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this \_\_\_\_\_ day of \_\_\_\_\_, 2009.

---

Warren C. Rolen



**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**Case No. 09-040-RPH-S**

**Case No. 09-040-PH-S**

**v.**

**WARREN C. ROLAN, R.Ph.,  
Certificate of Registration No: #15406**

**MOUNTAIN VIEW PHARMACY,  
Certificate of Registration No. PH01993**

**Respondents.**

---

**JOINT ANSWER, NOTICE OF DEFENSE, REQUEST FOR HEARING, DEMAND FOR  
DISCOVERY, OBJECTION TO TESTIMONY BY WAY OF DECLARATION,  
AFFIDAVIT OR REPORT/REQUEST FOR HEARING**

Comes Now, Respondents Warren C. Rolan, R.Ph., and Mountain View Pharmacy, by and through their undersigned counsel of record, Richard A. Schonfeld, Esq., of the law offices of Chesnoff & Schonfeld, and John V. Spilotro, Esq., and in Answer to the Notice of Intended Action and Accusation filed in the above entitled matter before the Nevada State Board of Pharmacy, declare and Answer as follows:

1. Answering Paragraph I of The Notice of Intended Action and Accusation, the Respondents are without sufficient information with which to form a basis as to the truth of the matters asserted and therefore deny said allegations in their entirety;

2. Answering Paragraph II of The Notice of Intended Action and Accusation, the Respondents are without sufficient information with which to form a basis as to the truth of the matters asserted and therefore deny said allegations in their entirety;

1  
2 3. Answering Paragraph III of The Notice of Intended Action and Accusation, the  
3 Respondents are without sufficient information with which to form a basis as to the truth of the  
4 matters asserted and therefore deny said allegations in their entirety;

5 4. Answering Paragraph IV of The Notice of Intended Action and Accusation, the  
6 Respondents are without sufficient information with which to form a basis as to the truth of the  
7 matters asserted and therefore deny said allegations in their entirety;

8 5. Answering Paragraph V of The Notice of Intended Action and Accusation, the  
9 Respondents are without sufficient information with which to form a basis as to the truth of the  
10 matters asserted and therefore deny said allegations in their entirety;

11 6. Answering Paragraph VI of The Notice of Intended Action and Accusation, the  
12 Respondents deny the allegations set forth;

13 7. Answering Paragraph VII of The Notice of Intended Action and Accusation, the  
14 Respondents deny the allegations set forth;

15 8. Answering Paragraph VIII of The Notice of Intended Action and Accusation, the  
16 Respondents deny the allegations set forth;

17 9. Answering Paragraph IX of The Notice of Intended Action and Accusation, the  
18 Respondents are without sufficient information with which to form a basis as to the truth of the  
19 matters asserted and therefore deny said allegations in their entirety;

20 10. Answering Paragraph X of The Notice of Intended Action and Accusation, the  
21 Respondents are without sufficient information with which to form a basis as to the truth of the  
22 matters asserted and therefore deny said allegations in their entirety;

23 11. Answering Paragraph XI of The Notice of Intended Action and Accusation, the  
24 Respondents deny the allegations set forth;

1  
2 12. Answering Paragraph XII of Plaintiff's Complaint, the Respondents deny the  
3 allegations set forth;

4 13. Answering Paragraph XIII of The Notice of Intended Action and Accusation, the  
5 Respondents deny the allegations set forth;

6 14. Answering Paragraph XIV of The Notice of Intended Action and Accusation, the  
7 Respondents deny the allegations set forth;

8 15. Answering Paragraph XV of The Notice of Intended Action and Accusation, the  
9 Respondents deny the allegations set forth;

10 16. Answering Paragraph XVI of The Notice of Intended Action and Accusation, the  
11 Respondents deny the allegations set forth;

12 **DEMAND FOR DISCOVERY**

13 Respondents hereby demands discovery pursuant to NRS 622A.330 including  
14 all documents and other evidence intended to be presented by the prosecutor in support of the case  
15 and a list of proposed witnesses.

16 Request for discovery is also made pursuant to NRS 639.2485.

17 **OBJECTION TO USE OF AFFIDAVITS, DECLARATIONS, OR REPORTS AS**  
18 **EVIDENCE**

19 The Board is hereby placed on notice that Respondents objects to the use of Affidavits,  
20 Declarations or Reports, as substantive evidence or as testimony in this manner under Crawford v.  
21 Washington, City v. Walsh, the Confrontation Clause of the United States Constitution and Nevada  
22 Constitution, as well as all other applicable statutes.

23 Objection is also made under NRS 639.248.

1  
2 DEFENSES

3 FIRST DEFENSE

4 The Complaint herein fails to state a claim against Respondents upon which relief can be  
5 granted.

6 SECOND DEFENSE

7  
8 The Board is estopped from pursuing any claim against Respondents.

9 THIRD DEFENSE

10  
11 The Board is barred by the doctrine of waiver.

12 FOURTH DEFENSE

13 Any claim of the Board is barred by the laches of the Board in pursuing such claim.

14 FIFTH DEFENSE

15  
16 The Respondents committed no wrongdoing during the time frame in question and this  
17 action should therefore be dismissed.

18 SIXTH DEFENSE

19  
20 The allegations against Respondents are vague and ambiguous and do not adequately  
21 provide the Respondents with notice and an opportunity to defend themselves.

22 SEVENTH DEFENSE

23  
24 The evidence obtained in this investigation was obtained in violation of the Respondents'  
25 constitutional rights.

EIGHTH DEFENSE

Pursuant to NRCP 11, as amended, all possible defenses may not have been alleged herein insofar as sufficient facts were not available after reasonable inquiry upon the filing of Respondents' Answer, and therefore Respondents reserve the right to amend this Answer to allege additional defenses if subsequent investigation warrants.

NINTH AFFIRMATIVE DEFENSE

Defendant incorporates herein by reference all defenses enumerated in Rule 8 of the Nevada Rules of Civil Procedure as if fully set forth herein. These defenses are incorporated by reference for the specific purpose of not waiving them.


REQUEST FOR HEARING

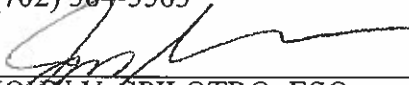
The Respondents hereby request a full hearing on the allegations that have been lodged against them.

DATED this 28<sup>th</sup> day of December, 2009.

Under Penalty of Perjury the undersigned does hereby affirm that they are counsel of record for the Respondents in these matters, and that this document constitutes the Respondents' Notice of Defense for purposes of NRS 639.244.

RESPECTFULLY SUBMITTED:

  
RICHARD A. SCHONFELD, ESQ.  
Nevada Bar No. 6815  
520 South Fourth Street  
Las Vegas, Nevada 89101  
(702) 384-5563

  
JOHN V. SPILOTRO, ESQ.  
Nevada Bar No. 4134  
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**COPY**

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**Case No. 09-040-RPH-S**

**Case No. 09-040-PH-S**

**v.**

**WARREN C. ROLAN, R.Ph.,  
Certificate of Registration No: #15406**

**MOUNTAIN VIEW PHARMACY,  
Certificate of Registration No. PH01993**

**Respondent.**

---

**RESPONDENTS' JOINT MOTION FOR DISCOVERY, FOR ISSUANCE OF  
SUBPOENAS, AND FOR CONTINUANCE OF HEARING SCHEDULED FOR JANUARY  
14, 2010**

Comes Now, Respondents Warren C. Rolan, R.Ph., and Mountain View Pharmacy, by and through their undersigned counsel of record, Richard A. Schonfeld, Esq., of the law offices of Chesnoff & Schonfeld, and John V. Spilotro, Esq., and hereby Moves for Discovery, for Issuance of Subpoenas, and for a Continuance of the January 14, 2010, hearing.

This Motion is made and based upon the papers and pleadings on file herein, the attached

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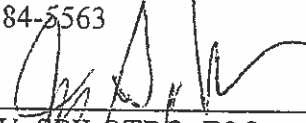
Memorandum of Points and Authorities, and any argument that may be heard.

DATED this 28<sup>th</sup> day of December, 2009.

RESPECTFULLY SUBMITTED:



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MEMORANDUM OF POINTS AND AUTHORITIES

Pursuant to NRS 639.2485 the Board is to authorize the issuance of Subpoenas for discovery purposes in these proceedings.

Pursuant to NRS 622A.330 the Respondents are entitled to all evidence that may be presented to the Board in support of the allegations against Respondents.

Additionally, pursuant to NRS 622A.330 the Respondents are entitled to receive a list of proposed witnesses that will be presented against them.

In light of the foregoing, the Respondents request all evidence that may be used against them, a list of witnesses that will be presented against them, and issuance of the following subpoenas:

1. Duces Tecum for all medical records related to Claudia Cannon and/or the patient referenced in the Notice of Intended Action and Accusation that allegedly died at Passavant Area Hospital in Jacksonville, Illinois, from August 18, 2008 through May 15, 2009.

The basis for this request is in order to respond to the Second Cause of Action in the Complaint wherein it is alleged that Respondent did not confirm that a physical examination had occurred within the last six months before the prescription was allegedly written by Respondent Rolan. These records are required to demonstrate that Claudia Cannon had in fact been physically examined within six months prior to the alleged prescriptions.

2. Subpoena Duces Tecum to Yashwant Amin, for all records in the possession of the Illinois Department of Financial and Professional Regulation related to Claudia Cannon;

3. Subpoena Duces Tecum to Dr. Gloria C. Fong for all records related to Claudia Cannon;

4. Subpoena Duces Tecum to Dr. Charles Myers for all records related to Claudia Cannon;

5. Subpoena Duces Tecum to Dr. Jack Edward Pickering for all records related to Claudia



1 Cannon;

2  
3 6. Subpoena Duces Tecum to the Morgan County Coroner for the autopsy and toxicology  
4 report related to the death of Claudia Cannon;

5 7. Subpoena Duces Tecum to Federal Bureau of Investigations Agent John Buma for all FBI  
6 302 reports, or other reports, related to the death of Claudia Cannon;

7  
8 8. Subpoena Duces Tecum to Federal Bureau of Investigations Agent John Buma for all FBI  
9 302 reports, or other reports, related to Warren Rolen and/or Mountain View Pharmacy;

10 9. Subpoena Duces Tecum to Pharmakind for all records related to Claudia Cannon;

11 10. Subpoena Duces Tecum to Alliance Health Group for all records related to Claudia  
12 Cannon;

13 **MOTION FOR CONTINUANCE**

14  
15 Pursuant to NAC 639.120 the Respondents are requesting a continuance of the hearing so  
16 that they can conduct discovery, can receive evidence that is intended to be used against them at  
17 the Board proceedings, and so they can adequately defend themselves herein.

18 Nevada law is clear that a Respondent to an administrative proceeding is guaranteed due  
19 process. *Bivins Construction v. State Contractors' Board*, 107 Nev. 281, 283. The Respondent is  
20 entitled to notice of the issues on which decisions will turn and the factual material on which the  
21 agency relies for decision so that he may rebut it. *Bowman Transportation v. Ark.-Best Freight*  
22 *System*, 419 U.S. 281, 288-89.

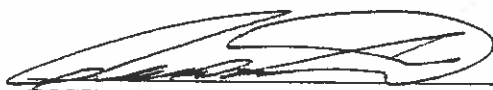
23  
24 The Board commenced its investigation in May of 2009, and proposes to provide  
25 Respondent with approximately thirty days within which to formulate its defense. If the hearing is  
26 not continued to afford the Respondent adequate time to receive and review the evidence in  
27 possession of the board, issue subpoenas, file Motions, and prepare their defense, the Respondents'  
28

1  
2 due process rights will be violated.

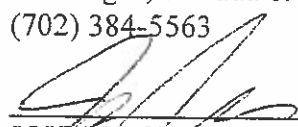
3 For the foregoing reasons it is respectfully requested that the Board issue the above stated  
4 Subpoenas, require production of discovery and a list of witnesses, and continue the hearing  
5 scheduled for January 14, 2010.

6 DATED this 28<sup>th</sup> day of December, 2009.  
7  
8

9 RESPECTFULLY SUBMITTED:

10  
11 

12 RICHARD A. SCHONFELD, ESQ.  
13 Nevada Bar No. 6815  
14 520 South Fourth Street  
15 Las Vegas, Nevada 89101  
16 (702) 384-5563

17   
18 JOHN V. SPILOTRO, ESQ.  
19 Nevada Bar No. 4134  
20 626 South Sixth Street  
21 Las Vegas, Nevada 89101  
22  
23  
24  
25  
26  
27  
28



**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**v.**

**NOTICE OF INTENDED ACTION  
AND ACCUSATION**

**WARREN C. ROLAN, R.Ph.,  
Certificate of Registration No: #15406,**

**Case No. 09-040-RPH-S**

**MOUNTAIN VIEW PHARMACY,  
Certificate of Registration No: PH01993,**

**Case No. 09-040-PH-S**

**Respondents.**

\_\_\_\_\_/

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.

I.

The Nevada State Board of Pharmacy has jurisdiction over this matter because Respondent Warren C. Rolan is a pharmacist licensed by the Board and Respondent Mountain View Pharmacy (Mountain View) is a pharmacy licensed by the Board located at 3150 North Tenaya Way #170, Las Vegas, Nevada.

II.

On May 26, 2009, the Board received a letter and supporting documentation from Yashwant Amin, RPh, PhD., Director of Drug Compliance for the Illinois Department of Financial and Professional Regulation notifying the Board that a patient had died at Passavant Area Hospital in Jacksonville, Illinois after purchasing and

consuming drugs from the internet. The letter was sent to inform the Board that a pharmacy in Nevada might have been involved in the sale and dispensing of medications to the deceased patient. The complaint also detailed the death of the Illinois patient and was accompanied with a list of medications that were recovered from the decedent's residence.

### III.

The list detailed the pharmacy name, pharmacy address, pharmacy phone number, prescribing physician, filling pharmacist's initials, date filled, and comments. All medications on the list were either carisoprodol 350mg. #180 or Tramadol 50mg. #180. The list identified Mountain View Pharmacy, located at 3150 North Tenaya Way, Suite 170 in Las Vegas, Nevada 89128 with the telephone number (866) 465-0791, as having filled three prescriptions for carisoprodol 350mg. #180 for the deceased patient. The list showed that the first prescription was filled by Mountain View on February 19, 2009 with the filling pharmacists initials of RK prescribed by Dr. Gloria C. Fong with the comment "different 1<sup>st</sup> name on script;" the second on April 10, 2009 with the filling pharmacists initials of RK prescribed by Dr. Charles Myers; and the third on March 26, 2009 with the pharmacists initials of RK prescribed by Dr. Jack Edward Pickering. Neither Dr. Fong, Dr. Myers, nor Dr. Pickering are physicians licensed in Nevada.

### IV.

Morgan County Coroner, Jeff Lair, identified the deceased patient as 59-year-old Claudia Cannon from Chapin, Illinois. Ms. Cannon's date of death was May 15, 2009. Ms. Cannon's death was ruled as accidental caused by Acute Liver Failure, Toxic Liver Damage and Chronic Ultracet (Tramadol) Abuse.

V.

Special Agent John Buma from the F.B.I. Springfield, Illinois office confirmed that a large number of prescription medication bottles were recovered from Claudia Cannon's residence and impounded by his office. Special Agent Buma confirmed that over 7,000 dosage units of carisoprodol 350 mg tablets or Tramadol 50mg tablets from prescriptions obtained through the internet from about seven different states were impounded. Special Agent Buma stated that three bottles of medications from Mountain View had been impounded on scene.

VI.

Warren Rolen, the Owner/Pharmacy Manager for Mountain View was contacted and identified four prescriptions that he filled for Claudia Cannon:

1. Order #85713 carisoprodol 350mg. #180 dated 2/19/09
2. Order #99817 Tramadol 50mg. #180 dated 3/13/09
3. Order #99808 Soma 350mg. #180 dated 3/36/09
4. Order #118102 Soma 350mg. #180 dated 4/10/09

VII.

On June 5, 2008, Warren Rolen received a fax from PHARMAKIND, a subsidiary of Alliance Health Group promoting an internet pharmacy business. Warren Rolen stated that he never signed up for the business but that prescriptions were sent to him online after the patient filled out an online questionnaire. Warren Rolen stated that the prescriptions were usually for carisoprodol (a CIV controlled substance) and Tramadol (a dangerous drug). The prescriptions had the physician's name, address, telephone number, license number and DEA number listed. Warren Rolen at first contacted some of the physicians telephonically to verify the authenticity of the prescriptions, but later

ceased this activity and filled the prescriptions without contacting the physicians. Warren Rolen stated that he would accept or reject the prescriptions and on the prescriptions that he would accept to fill later in the day, he would print labels, patient profiles, prescriptions and mailing labels at Mountain View. The prescriptions would then be filled and mailed using DHL initially and then later on Federal Express as the shipper. Warren Rolen kept the records for his internet business in boxes in a storage room inside the pharmacy in no chronological order. Additionally, the patient profiles for the internet pharmacy were only retrievable through the internet computer and only by specific prescription. Warren Rolen's internet prescription business and computer system was separate from Warren Rolen's Mountain View computer system. Warren Rolen never reported the filling of any internet pharmacy prescription to the Nevada Controlled Substance Task Force.

#### VIII.

Warren Rolen had the original downloaded prescriptions for three of the four prescriptions that he filled for Claudia Cannon via PHARMAKIND. The missing prescription, Order #118102 was for Soma, but there was a Federal Express delivery confirmation notice for the prescription that confirmed it had been sent to Claudia Cannon. Warren Rolen admitted that he had filled over 5000 prescriptions under the internet service PHARMAKIND and did not verify the authenticity of any doctor/patient relationship for any of Claudia Cannon's prescriptions.

#### IX.

Mountain View was not registered as an internet pharmacy and was not licensed in any other state as an out-of-state or internet pharmacy.

X.

Warren Rolan voluntarily submitted his Wells Fargo bank account records which show 42 deposits totaling \$117,000.00 from PHARMAKIND, from June 6, 2008 through May 21, 2009.

**FIRST CAUSE OF ACTION**

XI.

For acting as an internet pharmacy without appropriate licensure and or certification, Respondents Warren Rolan and Mountain View have violated NRS 453.3618 and/or NRS 453.3638(1) and/or NRS 639.210(4) and/or NRS 639.23288(1)(a) and/or NAC 639.426(1) and/or NAC 639.945(1)(k).

**SECOND CAUSE OF ACTION**

XII.

For failing to establish that a bona fide relationship existed between the Claudia Cannon and the doctors who wrote her prescriptions by confirming that a physical examination had occurred within the last six months before the prescription was written, Respondent Warren Rolan violated NRS 639.235 and/or 639.210(4) and/or NAC 639.945(1)(i).

**THIRD CAUSE OF ACTION**

XIII.

For failing to maintain prescription records in chronological order, Respondent Warren Rolan violated NRS 639.210(4) and/or NAC 639.706(1),(2) and (3) and/or NAC 639.945(1)(i).



#### **FOURTH CAUSE OF ACTION**

XIV.

For failing to report to the Nevada Controlled Substance Task Force the controlled substance prescriptions for Claudia Cannon and all of the other prescriptions filled for PHARMAKIND that were controlled substances, Respondents Warren Rolen and Mountain View have violated NRS 639.210(4) and/or NAC 639.926(1) and/or NAC 639.945(1)(i).

#### **FIFTH CAUSE OF ACTION**

XV.

For failing to provide a toll-free telephone number to provide telephonic counseling for patients being served out-of-state, Respondents Warren Rolen and Mountain View have violated NRS 639.210(4) and/or NAC 639.708(4)(a) and/or NAC 639.945(1)(i).

#### **SIXTH CAUSE OF ACTION**

XVI.

For failing to provide written patient information as provided for in NAC 639.707(1) and (2) and failing to review patient records regarding overutilization of the drug and drug abuse which contributed to the death of Claudia Cannon, Respondent Warren Rolen, violated NRS 639.210(4) and/or NAC 639.707(3) and (4) and/or NAC 639.945(1)(i).

#### **SEVENTH CAUSE OF ACTION**

XVI.

In participating in a course of action intended to assist in the fraudulent and deceitful purchasing of medications, including controlled substances, via the

internet with knowledge that, or under circumstances that Respondents Warren Rolan and Mountain View should have reasonably known that the sale of the medications were unlawful, questionable, or illegal, Respondents Warren Rolan and Mountain View violated NRS 639.210(4) and/or (12) and NAC 639.945(1)(h), and (i). Pursuant to NAC 639.955(7), all four orders that were filled and sent to Claudia Cannon by Respondents are grouped in this cause of action for the Board's administrative convenience, but the Board may impose separate discipline for each of the four orders.

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 10<sup>th</sup> day of December, 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,**

**v.**

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

**MOUNTAIN VIEW PHARMACY  
Certificate of Registration No. PH01993**

**Case No. 09-040-PH-S**

**Respondent.**

\_\_\_\_\_/

**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.

**II.**

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. 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.

III.

The Board has reserved Wednesday, January 13, 2010 as the date for a hearing on this matter at the Las Vegas Chamber of Commerce, 6671 Las Vegas Boulevard South, Las Vegas, 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 30<sup>th</sup> day of December, 2009.

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

**ORIGINAL**

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**v.**

**ANSWER AND NOTICE  
OF DEFENSE**

**MOUNTAIN VIEW PHARMACY  
Certificate of Registration No. PH01993**

**Case No. 09-040-PH-S**

**Respondent.**

\_\_\_\_\_/

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").

"See Attached"

///

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

"See Attached?"

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this \_\_\_\_\_ day of \_\_\_\_\_, 2009.

\_\_\_\_\_  
type or print name

\_\_\_\_\_  
For Mountain View Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**Case No. 09-040-RPH-S**

**Case No. 09-040-PH-S**

**v.**

**WARREN C. ROLAN, R.Ph.,  
Certificate of Registration No: #15406**

**MOUNTAIN VIEW PHARMACY,  
Certificate of Registration No. PH01993**

**Respondents.**

---

**JOINT ANSWER, NOTICE OF DEFENSE, REQUEST FOR HEARING, DEMAND FOR  
DISCOVERY, OBJECTION TO TESTIMONY BY WAY OF DECLARATION,  
AFFIDAVIT OR REPORT/REQUEST FOR HEARING**

Comes Now, Respondents Warren C. Rolan, R.Ph., and Mountain View Pharmacy, by and through their undersigned counsel of record, Richard A. Schonfeld, Esq., of the law offices of Chesnoff & Schonfeld, and John V. Spilotro, Esq., and in Answer to the Notice of Intended Action and Accusation filed in the above entitled matter before the Nevada State Board of Pharmacy, declare and Answer as follows:

1. Answering Paragraph I of The Notice of Intended Action and Accusation, the Respondents are without sufficient information with which to form a basis as to the truth of the matters asserted and therefore deny said allegations in their entirety;

2. Answering Paragraph II of The Notice of Intended Action and Accusation, the Respondents are without sufficient information with which to form a basis as to the truth of the matters asserted and therefore deny said allegations in their entirety;

1  
2 3. Answering Paragraph III of The Notice of Intended Action and Accusation, the  
3 Respondents are without sufficient information with which to form a basis as to the truth of the  
4 matters asserted and therefore deny said allegations in their entirety;

5 4. Answering Paragraph IV of The Notice of Intended Action and Accusation, the  
6 Respondents are without sufficient information with which to form a basis as to the truth of the  
7 matters asserted and therefore deny said allegations in their entirety;

8 5. Answering Paragraph V of The Notice of Intended Action and Accusation, the  
9 Respondents are without sufficient information with which to form a basis as to the truth of the  
10 matters asserted and therefore deny said allegations in their entirety;

11 6. Answering Paragraph VI of The Notice of Intended Action and Accusation, the  
12 Respondents deny the allegations set forth;

13 7. Answering Paragraph VII of The Notice of Intended Action and Accusation, the  
14 Respondents deny the allegations set forth;

15 8. Answering Paragraph VIII of The Notice of Intended Action and Accusation, the  
16 Respondents deny the allegations set forth;

17 9. Answering Paragraph IX of The Notice of Intended Action and Accusation, the  
18 Respondents are without sufficient information with which to form a basis as to the truth of the  
19 matters asserted and therefore deny said allegations in their entirety;

20 10. Answering Paragraph X of The Notice of Intended Action and Accusation, the  
21 Respondents are without sufficient information with which to form a basis as to the truth of the  
22 matters asserted and therefore deny said allegations in their entirety;

23 11. Answering Paragraph XI of The Notice of Intended Action and Accusation, the  
24 Respondents deny the allegations set forth;



12. Answering Paragraph XII of Plaintiff's Complaint, the Respondents deny the allegations set forth;

13. Answering Paragraph XIII of The Notice of Intended Action and Accusation, the Respondents deny the allegations set forth;

14. Answering Paragraph XIV of The Notice of Intended Action and Accusation, the Respondents deny the allegations set forth;

15. Answering Paragraph XV of The Notice of Intended Action and Accusation, the Respondents deny the allegations set forth;

16. Answering Paragraph XVI of The Notice of Intended Action and Accusation, the Respondents deny the allegations set forth;

#### **DEMAND FOR DISCOVERY**

Respondents hereby demands discovery pursuant to NRS 622A.330 including all documents and other evidence intended to be presented by the prosecutor in support of the case and a list of proposed witnesses.

Request for discovery is also made pursuant to NRS 639.2485.

#### **OBJECTION TO USE OF AFFIDAVITS, DECLARATIONS, OR REPORTS AS EVIDENCE**

The Board is hereby placed on notice that Respondents objects to the use of Affidavits, Declarations or Reports, as substantive evidence or as testimony in this manner under Crawford v. Washington, City v. Walsh, the Confrontation Clause of the United States Constitution and Nevada Constitution, as well as all other applicable statutes.

Objection is also made under NRS 639.248.

DEFENSES

FIRST DEFENSE

The Complaint herein fails to state a claim against Respondents upon which relief can be granted.

SECOND DEFENSE

The Board is estopped from pursuing any claim against Respondents.

THIRD DEFENSE

The Board is barred by the doctrine of waiver.

FOURTH DEFENSE

Any claim of the Board is barred by the laches of the Board in pursuing such claim.

FIFTH DEFENSE

The Respondents committed no wrongdoing during the time frame in question and this action should therefore be dismissed.

SIXTH DEFENSE

The allegations against Respondents are vague and ambiguous and do not adequately provide the Respondents with notice and an opportunity to defend themselves.

SEVENTH DEFENSE

The evidence obtained in this investigation was obtained in violation of the Respondents' constitutional rights.

EIGHTH DEFENSE

Pursuant to NRCP 11, as amended, all possible defenses may not have been alleged herein insofar as sufficient facts were not available after reasonable inquiry upon the filing of Respondents' Answer, and therefore Respondents reserve the right to amend this Answer to allege additional defenses if subsequent investigation warrants.

NINTH AFFIRMATIVE DEFENSE

Defendant incorporates herein by reference all defenses enumerated in Rule 8 of the Nevada Rules of Civil Procedure as if fully set forth herein. These defenses are incorporated by reference for the specific purpose of not waiving them.


REQUEST FOR HEARING

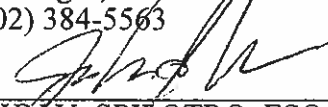
The Respondents hereby request a full hearing on the allegations that have been lodged against them.

DATED this 28<sup>th</sup> day of December, 2009.

Under Penalty of Perjury the undersigned does hereby affirm that they are counsel of record for the Respondents in these matters, and that this document constitutes the Respondents' Notice of Defense for purposes of NRS 639.244.

RESPECTFULLY SUBMITTED:

  
RICHARD A. SCHONFELD, ESQ.  
Nevada Bar No. 6815  
520 South Fourth Street  
Las Vegas, Nevada 89101  
(702) 384-5563

  
JOHN V. SPILOTRO, ESQ.  
Nevada Bar No. 4134  
626 South Sixth Street  
Las Vegas, Nevada 89101

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**NOTICE OF INTENDED ACTION  
AND ACCUSATION**

**v.**

**WILLIAM C. COLTON, PTT,  
Certificate of Registration No. PT08654,**

**Case No. 09-107-PTT-S**

**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.

**I.**

The Nevada State Board of Pharmacy has jurisdiction over this matter because Respondent Colton is a registered pharmaceutical technician in training with the Board.

**II.**

On or about October 26, 2009, Board staff was notified that Mr. Colton had been terminated from employment as a pharmaceutical technician at Walgreens #05154 located at 4905 West Tropicana Avenue, Las Vegas, Nevada on July 28, 2009. Another pharmaceutical technician at Walgreens #05154 observed Mr. Colton filling a prescription for Oxycodone and putting approximately five tablets in his smock. The pharmaceutical technician reported what she had seen to her managing pharmacist.

**III.**

The managing pharmacist and loss prevention personnel conducted an audit of their stock of hydrocodone 10/500 tablets, Alprazolam 0.25 tablets and Oxycodone 10/650 tablets and found shortages totaling 326 tablets.

IV.

In a voluntary written statement given as part of an exit interview with Walgreens loss prevention personnel, Mr. Colton admitted that he had diverted approximately 300 hydrocodone 10/500 tablets and 20 Xanax tablets for his personal use. The total loss to Walgreens was \$175.37, however Mr. Colton did not sign a promissory note to pay restitution to Walgreens before Las Vegas Metropolitan Police were called and embezzlement charges were filed against him.


**FIRST CAUSE OF ACTION**

V.

In removing controlled substances, namely hydrocodone 10/500. tablets and Xanax tablets, without a prescription therefore, Mr. Colton violated (NRS) 453.331(1)(d), 453.336(1) and 639.210(1), (4), and (12) and Nevada Administrative Code (NAC) 639.945(1)(h) and (i).

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 20<sup>th</sup> day of November, 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,**

**v.**

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

**WILLIAM C. COLTON, PTT  
Certificate of Registration No. PT08654,**

**Case No. 09-107-PTT-S**

**Respondent.**

\_\_\_\_\_/

**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.

**II**

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, January 14, 2010 as the date for a hearing on this matter at the Las Vegas Chamber of Commerce, 6671 Las Vegas Boulevard South, Las Vegas, 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 20<sup>th</sup> day of November, 2009.

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

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**v.**

**ANSWER AND NOTICE  
OF DEFENSE**

**WILLIAM C. COLTON, PTT,  
Certificate of Registration No. PT08654,**

**Case No. 09-107-PTT-S**

**Respondent.**

\_\_\_\_\_ /

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 Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this \_\_\_\_\_ day of \_\_\_\_\_, 2009.

---

William C. Colton, PTT

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

**NOTICE OF INTENDED ACTION  
AND ACCUSATION**

v.

JULIE E. WELLS, PT,  
Certificate of Registration No. PT06301,

Case No. 09-113-PT-S

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.

I.

The Nevada State Board of Pharmacy has jurisdiction over this matter because Respondent Julie Wells is a registered pharmaceutical technician with the Board.

II.

On or about November 23, 2009, Board staff was notified that Ms. Wells had been terminated from employment as a pharmaceutical technician at CVS Pharmacy #8787 (CVS #8787) located at 1050 Whitney Ranch Drive, Henderson, Nevada. It was discovered that Ms. Wells had been diverting controlled substances for her personal use.

III.

In a voluntary written statement given as part of an exit interview with CVS loss prevention personnel, Ms. Wells admitted that she had been diverting hydrocodone/APAP 10/500 since March, 2008. Ms. Wells admitted that she began taking one bottle of 100 per week but increased to four to five bottles per week as her addiction progressed. Ms. Wells would take full bottles of 100 from the pharmacy by

transferring the tablets to an empty Excedrin bottle. In her written statement Ms. Wells estimated that she had taken approximately 235 bottles of 100 hydrocodone 10/500 at a loss to CVS of approximately \$10,126.15

#### **FIRST CAUSE OF ACTION**

#### **IV.**

In removing controlled substances from her employing pharmacy without a prescription and without paying for them, namely hydrocodone/APAP 10/500, Ms. Wells violated (NRS) 453.331(1)(d), and/or 453.336(1) and/or 639.210(1), (4), and/or (12) and/or Nevada Administrative Code (NAC) 639.945(1)(h), and/or (i).

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 10<sup>th</sup> day of December, 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,**

**v.**

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

**JULIE E. WELLS, PT  
Certificate of Registration No. PT06301,**

**Case No. 09-113-PT-S**

**Respondent.**

\_\_\_\_\_/

**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.

**II**

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 Thursday, January 14, 2010 as the date for a hearing on this matter at the Las Vegas Chamber of Commerce, 6671 Las Vegas Boulevard South, Las Vegas, 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 10<sup>th</sup> day of December, 2009.

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

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**v.**

**ANSWER AND NOTICE  
OF DEFENSE**

**JULIE E. WELLS, PT,  
Certificate of Registration No. PT06301,**

**Case No. 09-113-PT-S**

**Respondent.**

\_\_\_\_\_ /

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 Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this \_\_\_\_\_ day of \_\_\_\_\_, 2009.

---

Julie E. Wells, PT

NEVADA STATE BOARD OF PHARMACY  
431 W. Plumb Lane ~ Reno, NV 89509 ~ (775) 850-1440  
PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION  
Registration Fee: \$40.00 - (non-refundable)

☒ New Application ☐ Change of Pharmacy ☐ Additional Pharmacy (Please check one)  
Complete Name (no abbreviations):

First: ANZON Middle: \_\_\_\_\_ Last: PABLO  
Home Address: 5317 STRAWBERRY TREE ST Apt #: \_\_\_\_\_  
City: N. LAS VEGAS State: NV Zip Code: 89103  
Telephone: \_\_\_\_\_ Social Security Number: \_\_\_\_\_  
Date of Birth: \_\_\_\_\_ Place of Birth: SAN DIEGO, CA Sex: (M) or F  
E-mail Address: \_\_\_\_\_

**I am requesting registration at the following pharmacy or approved training program:**

Pharmacy: PMA MEDICAL INSTITUTION Store #: N/A  
Address: 3333 E. FLAMINGO RD  
City: LAS VEGAS State: NV Zip Code: 89121  
Signature of Managing Pharmacist: Stewart E. Fecan Lic #: PL0139 Date: 7/14/09

(Without the signature of the managing pharmacist, the application will be returned.)

- 1) Are you 18 years of age or older? Yes ☒ No ☐  
2) Are you a high school graduate or the equivalent? Yes ☒ No ☐  
(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)  
3) I have ☐ I have not ☒ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse.  
4) I have ☒ I have not ☐ been charged, arrested or convicted of a misdemeanor ☒ or felony ☐  
5) I have ☐ I have not ☒ been the subject of an administrative action whether completed or pending.  
6) I have ☐ I have not ☒ had a professional license suspended, revoked, surrendered or otherwise disciplined, including any action against my license that was not made public.

If you checked "I have" to questions 3 thru 6, please include the following information and provide documentation and/or an explanation.

a) Board Administrative Action and/or State: \_\_\_\_\_ Date: \_\_\_\_\_ Case #: \_\_\_\_\_  
b) Criminal Action County: CLARK State: NV Date: 7/20/09 Case #: C253079  
Court: SEVENTH JUDICIAL DISTRICT COURT

In response to federally mandated requirements, the Nevada Legislature and Attorney General require that we include the following questions as part of all applications.

I am ☐ I am not ☒ subject to a court order for the support of a child.

**IF YOU ARE SUBJECT** to a court order for the support of a child, please mark the appropriate response.

I am ☐ I am not ☐ in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order for the support of one or more children.

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians in training and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit.

Signature: \_\_\_\_\_

Date: 07/20/09

Board Use Only

Received: REC. 08/05/09 Check Number: 710 Amount: 40.00

52572  
7322



NEVADA STATE BOARD OF PHARMACY  
431 W. Plumb Lane ~ Reno, NV 89509 ~ (775) 850-1440  
PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION  
Registration Fee: \$40.00 - (non-refundable)

☒ New Application ☐ Change of Pharmacy ☐ Additional Pharmacy (Please check one)  
Complete Name (no abbreviations):

First: GENARO Middle: STEVEN Last: SICILIANO

Home Address: 4110 ROYALHILL AVE. Apt #: \_\_\_\_\_

City: LAS VEGAS State: NV Zip Code: 89121

Telephone: \_\_\_\_\_ Social Security Number: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Place of Birth: BROOKLYN, NYC Sex: ☒ M or F

E-mail Address: GENARO.SICILIANO@GMAIL.COM

I am requesting registration at the following pharmacy or approved training program:

Pharmacy: PIMA MEDICAL INSTITUTE Store #: N/A

Address: 3333 E. FLAMINGO RD

City: LAS VEGAS State: NV Zip Code: 89121

Signature of Managing Pharmacist: Steve L. Green, CPhT Lic #: PT00139 Date: 11/23/09

(Without the signature of the managing pharmacist, the application will be returned.)

- 1) Are you 18 years of age or older? Yes ☒ No ☐  
2) Are you a high school graduate or the equivalent? Yes ☒ No ☐  
(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)  
3) I have ☐ I have not ☒ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse.  
I have ☒ I have not ☒ been charged, arrested or convicted of a misdemeanor ☐ or felony ☐  
5) I have ☐ I have not ☒ been the subject of an administrative action whether completed or pending.  
6) I have ☐ I have not ☒ had a professional license suspended, revoked, surrendered or otherwise disciplined, including any action against my license that was not made public.

If you checked "I have" to questions 3 thru 6, please include the following information and provide documentation and/or an explanation.

a) Board Administrative Action State: \_\_\_\_\_ Date: \_\_\_\_\_ Case #: \_\_\_\_\_  
and/or

b) Criminal Action State: NEVADA Date: 10/25/09 Case #: \_\_\_\_\_  
County: CLARK Court: CLARK COUNTY

In response to federally mandated requirements, the Nevada Legislature and Attorney General require that we include the following questions as part of all applications.

I am ☐ I am not ☒ subject to a court order for the support of a child.

**IF YOU ARE SUBJECT** to a court order for the support of a child, please mark the appropriate response.

I am ☐ I am not ☐ in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order for the support of one or more children.

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians in training and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit.

Signature

Date

and Use Only

Received:

Check Number:

Amount:

52573  
7345

**Genaro Siciliano**

**4110 Royalhill Ave. Las Vegas, NV  
89121**

To: The Nevada State Board of Pharmacy

My name is Genaro Siciliano and I would like to explain my situation concerning my arrest on October 25<sup>th</sup> 2009. The morning of, my fiancé and I had a minor dispute regarding some issues we were trying to work out. We exchanged words that were less than appropriate wherein she left to a friend's house. My fiancé's friend, after hearing that her and I got into a verbal fight, called the police and was asked if there were any weapons in the house. Her friend then told the police that I had a shotgun in the house. While in miscommunication the police showed up at my house while I was sitting in my front lawn with weapons pointed at me. I then stood up and asked the officers what was going on and why they were there. They advised me they got a call about domestic disturbance involving a shotgun and asked me where my shotgun was located. I informed the police my shotgun was locked inside my house unloaded. They then asked me to step off of my property and I asked if they had a search warrant. They informed me they did not have a search warrant and immediately responded with get off your property. I confessed to the police officers that I don't have a record and am in the military and I can speak to them from my yard in a calm and collected voice. One of the officers then yelled out, "You're Obstructing Justice! Get on the floor and put your hands on your head." I immediately complied and was arrested for obstructing justice and not stepping off my property when asked to by police. My court date is on December 2<sup>nd</sup> 2009 and I have not been convicted of a crime. The crime is a misdemeanor and I am going to be working with an attorney after my Pre-Trial on December 2<sup>nd</sup>. It would be nice to know that this letter is taken into consideration when being reviewed for my Pharmacy Technician State License and thank you for taking the time to read this.

Thank You,

A handwritten signature in black ink, appearing to read 'Genaro Siciliano', with a stylized, flowing script.

Mr. Genaro Siciliano

**NEVADA STATE BOARD OF PHARMACY**  
431 W Plumb Lane ~ Reno, NV 89509 ~ (775) 850-1440  
**APPLICATION BY EXAMINATION AS A PHARMACIST**

**Total Fee: \$300.00 (non-refundable, money order or cashier's check only)**

Money Order or Cashier's Check made payable to: **Nevada State Board of Pharmacy**

Complete Name (no abbreviations):

First: David Middle: James Last: Katsules

Mailing Address: 2797 Grande Valley Drive

City: Las Vegas State: NV Zip Code: 89135

Telephone: \_\_\_\_\_ Social Security Number: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Place of Birth: Portland, Oregon Sex: ☒ M ☐ F

E-mail Address: dkatsules@earthlink.net

**College of Pharmacy Information**

Graduation Date: 06/11/1989

(mm/dd/yy)

Degree Received: ☐ PharmD ☒ BS in Pharmacy ☐ Other (check one)

Name of Pharmacy School: Oregon State University College of Pharmacy

Location of School: Corvallis, Oregon

If you are a **foreign graduate** you must attach a copy of your FPGEC certificate to THIS APPLICATION. You also need to complete the college of pharmacy information.

Other states where you are (or were) licensed as a pharmacist or print "none"

State	License #	Is the license active?	State	License #	Is the license active?
<u>OR</u>	<u>7922</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	<u>OR</u>	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>
_____	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	<u>NV</u>	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>
_____	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>

**Board Use Only**

Received: DEC 4 9 2009 Check Number: MO Amount: 300.00

Date Law Book Mailed: 12/10 NAPLEX/MPJE Approved: \_\_\_\_\_

- 1) I have ☒ I have not ☐ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse.
- 2) I have ☒ I have not ☐ been charged, arrested or convicted of a felony or misdemeanor.
- 3) I have ☒ I have not ☐ been the subject of an administrative action whether completed or pending.
- 4) I have ☒ I have not ☐ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against my license that was not made public.

If you checked "I have" to questions 2, 3 or 4 above, please include the following information and an explanation and/or documents.

a) Board Administrative Action and/or State: OR Date: April 2005 Case Number 2004-0312

b) Criminal Action State: NV Date: 8/23/2004 Case Number: \_\_\_\_\_

County: Clark Court: \_\_\_\_\_

=====

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**FEDERALLY MANDATED REQUIREMENTS**

In response to Federally mandated requirements, the Nevada Legislature and Attorney General require that we include this form as part of all applications

I am ☐ I am not ☒ subject to a court order for the support of a child.

If you are subject to a court order for the support of a child, please mark the appropriate response.

I am ☐ I am not ☐ in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order for the support of one or more children.

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, it's agents, servants and employees, to conduct any investigation(s) of my business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

No liability of any sort or kind shall attach to the said Nevada State Board of Pharmacy, it's members, servants or employees because or by reason of the use of the authorization.

  
\_\_\_\_\_  
SIGNATURE OF APPLICANT

\_\_\_\_\_  
11/29/2009  
DATE

November 29, 2009

Dear Sir or Ma'am;

In August, 2004 I was in a motor vehicle accident and charged with driving under the influence of alcohol in Las Vegas, NV. When I reported this to the Oregon State Board of Pharmacy, I was required to undergo treatment for alcohol dependence and enroll in a monitoring program.

The Oregon Board of Pharmacy approved my request to be monitored in Nevada by Larry Espadero and have been fulfilling my obligations as stated in the PRN contract since January, 2006.

I apologize that I no longer have the case number or citation number of the DUI charge. I appreciate the opportunity to apply for a pharmacist license in Nevada.

Sincerely,

A handwritten signature in black ink, appearing to read "David J. Katsules". The signature is fluid and cursive, with the first name "David" being more prominent.

David J. Katsules

## Board of Pharmacy

### Verification Details for:

---

Details as of: 12-09-2009 09:00:20 AM PST

Name: **DAVID J KATSULES**

City: **LAS VEGAS**      State: **NV**

License Number	Type	Issue Date	Last Renewal	Status	Expiration Date	Discipline
RPH-0007922	Pharmacist	09-27-1989	05-05-2009	Active	06-30-2010	<u>Contact OBOP</u>

[Print](#)

[Help](#)

[Close](#)

**NEVADA STATE BOARD OF PHARMACY**  
431 W Plumb Lane ~ Reno, NV 89509 ~ (775) 850-1440  
**APPLICATION BY RECIPROCATATION AS A PHARMACIST**

**Total Fee: \$300.00 (non-refundable, money order or cashier's check only)**

Money Order or Cashier's Check made payable to: **Nevada State Board of Pharmacy**

Complete Name (no abbreviations):

First: Madonna Middle: Rose Last: Wilcox

Mailing Address: 5596 B Lakeview Circle

City: Osage Beach State: Missouri Zip Code: 65065

Telephone: \_\_\_\_\_ Social Security Number: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Place of Birth: St. Louis Missouri ☐ M ☒ F

E-mail Address: madonna\_rph@yahoo.com

**College of Pharmacy Information**

Graduation Date: 5/15/1982  
(mm/dd/yy)

Degree Received: ☐ PharmD ☒ BS in Pharmacy ☐ Other (check one)

Name of Pharmacy School: St. Louis College of Pharmacy

Location of School: Saint Louis Missouri

If you are a **foreign graduate** you must attach a copy of your FPGEC certificate to THIS APPLICATION. You also need to complete the college of pharmacy information.

State which are licensed by exam: Missouri

Other states where you are (or were) licensed as a pharmacist or print "none"

State	License #	Is the license active?	State	License #	Is the license active?
<u>MO</u>	<u>041012</u>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	_____	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>
_____	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>
_____	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>	_____	_____	Yes <input type="checkbox"/> No <input type="checkbox"/>

**Board Use Only**

Received: FEB 18 2009 Check Number: MO Amount: 300-  
Date Law Book Mailed: 2/25 MPJE Approved: \_\_\_\_\_

49350  
269

- 1) I have ☐ I have not ☒ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse.
- 2) I have ☐ I have not ☒ been charged, arrested or convicted of a felony or misdemeanor.
- 3) I have ☒ I have not ☐ been the subject of an administrative action whether completed or pending.
- 4) I have ☒ I have not ☐ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against my license that was not made public.

If you checked "I have" to questions 2, 3 or 4 above, please include the following information **and** an explanation and/or documents.

- a) Board Administrative Action and/or State: MO Date: 11/7/2006 Case Number: n/a
- b) Criminal Action State: \_\_\_\_\_ Date: \_\_\_\_\_ Case Number: \_\_\_\_\_  
County: \_\_\_\_\_ Court: \_\_\_\_\_

### **FEDERALLY MANDATED REQUIREMENTS**

In response to Federally mandated requirements, the Nevada Legislature and Attorney General require that we include this form as part of all applications

I am ☐ I am not ☒ subject to a court order for the support of a child.

If you **are** subject to a court order for the support of a child, please mark the appropriate response.

I am ☐ I am not ☐ in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order for the support of one or more children.

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, it's agents, servants and employees, to conduct any investigation(s) of my business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

No liability of any sort or kind shall attach to the said Nevada State Board of Pharmacy, it's members, servants or employees because or by reason of the use of the authorization.

Madonna Wilson Rte  
**SIGNATURE OF APPLICANT**

1/16/2009  
**DATE**





Matt Blunt  
Governor  
State of Missouri

David T. Broeker, Director  
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance  
Financial Institutions  
and Professional Registration  
Linda Bohrer, Acting Director

BOARD OF PHARMACY  
3605 Missouri Boulevard  
P.O. Box 625  
Jefferson City, MO 65102-0625  
573-751-0091 PHONE  
573-526-3464 FAX  
800-735-2966 TTY Relay Missouri  
800-735-2466 Voice Relay Missouri

[www.pr.mo.gov/pharmacists.asp](http://www.pr.mo.gov/pharmacists.asp)  
e-mail: [pharmacy@pr.mo.gov](mailto:pharmacy@pr.mo.gov)

November 7, 2008

Madonna R Wilcox, RPh  
5596 B Lakeview Circle  
Osage Beach, MO 65065

Dear Ms. Wilcox:

This is official notification that you have completed the terms of your discipline with the Missouri Board of Pharmacy as of November 6, 2008. If you have any questions, or if we can be of assistance in the future, feel free to contact this office.

Thank you for complying.

Sincerely,

A handwritten signature in black ink, appearing to read "Don Walker".

DON WALKER  
COMPLIANCE COORDINATOR



Matt Blunt  
Governor  
State of Missouri

David T. Broeker, Director  
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance  
Financial Institutions  
and Professional Registration  
W. Dale Finke, Director

BOARD OF PHARMACY  
3605 Missouri Boulevard  
P.O. Box 625  
Jefferson City, MO 65102-0625

[www.pr.mo.gov/pharmacists.asp](http://www.pr.mo.gov/pharmacists.asp)  
e-mail: [pharmacy@pr.mo.gov](mailto:pharmacy@pr.mo.gov)  
573-751-0091 PHONE  
573-526-3464 FAX  
800-735-2966 TTY Relay Missouri  
800-735-2466 Voice Relay Missouri

November 7, 2006

Madonna R. Wilcox, RPh  
5596B Lakeview Circle  
Osage Beach, MO 65065

Dear Ms. Wilcox:

On October 23, 2006, you were sent an executed copy of the **Settlement Agreement Between State Board of Pharmacy and Madonna Wilcox**. Your Missouri pharmacist license #041012 was placed on probation, effective today, November 7, 2006 until November 6, 2008.

You should review each term of this Agreement and comply with the requirements as set forth, paying special attention to the sections regarding retaking the law exam and continuing education requirements. Compliance with this Agreement is your responsibility; reminders will not be sent from this office. Failure to comply with the terms of this Agreement may result in a violation hearing before the Board.

Enclosed is a Licensee Report of Discipline Compliance form for use in submitting the six-month reports required by the Agreement. This form may be copied as needed for future use.

Sincerely,

DON WALKER  
COMPLIANCE COORDINATOR

enclosure



Matt Blunt  
Governor  
State of Missouri

David T. Broeker, Director  
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance  
Financial Institutions  
and Professional Registration  
W. Dale Finke, Director

BOARD OF PHARMACY  
3605 Missouri Boulevard  
P.O. Box 625  
Jefferson City, MO 65102-0625

[www.pr.mo.gov/pharmacists.asp](http://www.pr.mo.gov/pharmacists.asp)  
e-mail: [pharmacy@pr.mo.gov](mailto:pharmacy@pr.mo.gov)  
573-751-0091 PHONE  
573-526-3464 FAX  
800-735-2966 TTY Relay Missouri  
800-735-2466 Voice Relay Missouri

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Certified Article Number

7160 3901 9849 2178 7664

SENDERS RECORD

October 23, 2006

Madonna R. Wilcox, RPh  
5596B Lakeview Circle  
Osage Beach, MO 65065

Dear Ms. Wilcox:

Enclosed is a copy of the fully executed **Settlement Agreement Between State Board of Pharmacy and Madonna R. Wilcox** regarding discipline of your Missouri license to practice pharmacy #041012.

The Agreement is scheduled to become effective November 7, 2006. You will receive additional communication from our office after that date. If you have any questions, please feel free to contact me at (573) 751-9056.

Sincerely,

DON WALKER  
COMPLIANCE COORDINATOR

dw

Enclosure

cc: William E. Roberts, AAG

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY  
AND MADONNA WILCOX**

Come now Madonna Wilcox ("Licensee") and the State Board of Pharmacy ("Board") and enter into this settlement agreement for the purpose of resolving the question of whether Licensee's pharmacist license will be subject to discipline.

Pursuant to the terms of § 536.060, RSMo 2000, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the state of Missouri and, additionally, the right to a disciplinary hearing before the Board under § 621.110, RSMo 2000, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Licensee acknowledges that she understands the various rights and privileges afforded her by law, including the right to a hearing of the charges against her; the right to appear and be represented by legal counsel; the right to have all charges against her proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against her; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against her and, subsequently, the right to a disciplinary hearing before the Board at which time she may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against her license. Being aware of these rights provided her by operation of law, Licensee knowingly and voluntarily waives each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to her.

Licensee acknowledges that she has received a copy of the complaint filed with the Board, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Licensee's license. For the purpose of settling this dispute, Licensee stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Licensee's pharmacist license, License Number 41012 is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621, RSMo 2000 and Chapter 338, RSMo 2000.

Joint Stipulation of Facts

1. The Missouri Board of Pharmacy ("Board") is an agency of the state of Missouri, created and established pursuant to § 338.140, RSMo<sup>1</sup>, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Madonna Wilcox ("Licensee") is licensed by the Board as a pharmacist, License No. 41012. Licensee's Missouri license was at all times relevant herein, and is now, current and active.

3. At the time of the events described herein, Licensee was the Pharmacist-in-Charge at Osage Village Pharmacy ("Pharmacy").

4. On or about January 23, 2004, Inspector Sidney G. Werges ("Werges") conducted an inspection for the Board. At that time, the Pharmacy was distributing

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<sup>1</sup>All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise noted.

controlled substances in amount which exceeded 5% of the Pharmacy's total gross sales volume without a drug distributor's license.

5. During the January 23, 2004 inspection, Werges also noted that the Pharmacy was improperly using logs and labeling for batch compounding. Specifically, the Pharmacy's logs did not contain lot numbers.

6. On or about March 1, 2005, Werges and Inspector Tom Glenski ("Glenski") conducted another inspection at the Pharmacy. At this time, the Pharmacy was still out of compliance in regard to compounding. Specifically, the Pharmacy had incomplete compounding records for both batch and patient specific compounding.

7. During the March 1, 2005 inspection, Werges found twelve outdated manufacturer's stock bottles in the Pharmacy's active inventory. Werges also found a large cardboard box of outdated drugs in the Pharmacy that had not been disposed of.

8. During the March 1, 2005 inspection, Glenski found a prescription for Midrin in which a generic substitute had been dispensed. Glenski could not find a generic form of this drug in the active inventory. However, in the cardboard box of outdated drugs, Glenski found an outdated manufacturer's stock bottle Migquin, of the generic form of Midrin.

9. The outdated generic drug was labeled Migquin, NDC #0603-4664-24, Lot #K10302. The bottle was labeled with an expiration date of September, 2004.

10. When Werges asked Licensee how she filled the prescription for Midrin, Licensee told Werges that she had filled it with a small bottle she had ordered from the

wholesaler and had dispensed the whole bottle. Licensee stated that she had dispensed the entire bottle, thus none remained in the Pharmacy.

11. Werges and Glenski asked for the dispensing record for the generic Midrin for the time period beginning on October 1, 2004 and ending March 1, 2005. Licensee provided the record which showed two prescriptions for generic Midrin totaling 50 capsules.

12. The NDC number on the records for the two prescriptions for generic Midrin was the same as the NDC number on the outdated stock bottle of Migquin, NDC #0603-4664-24.

13. Qualitest Pharmaceuticals, the manufacturer of Migquin distributes only two different size stock bottles of Migquin: a 100-capsule stock bottle (NDC #0603-4664-21) and a 250-capsule stock bottle (NDC #0603-4664-24).

14. Werges and Glenski did not locate an invoice at the Pharmacy for generic Midrin or Migquin. They left a *Drug Utilization Review* form with Licensee requesting that she provide copies of the invoices for the purchases of such drugs.

15. On or about March 10, 2005, Werges received a response from Licensee stating that she could not find an invoice for the drugs.

16. On or about March 31, 2005, Werges interviewed Licensee. At that time, Licensee admitted that she had used outdated drugs to fill the prescriptions for Migquin.

Joint Conclusions of Law

17. § 338.055.2(5), (6), (13), and (15), RSMo, state, in pertinent part:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:

...

(5) Incompetency, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

...

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

...

(13) Violation of any professional trust or confidence;

...

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government[.]

...



18. § 338.333, RSMo, regulates the activity of wholesale drug distributors and pharmacy distributors and states, in pertinent part:

1. No person or distribution outlet shall act as a wholesale drug distributor or pharmacy distributor without first obtaining license to do so from the Missouri Board of Pharmacy and paying the required fee[.]

19. § 338.330.2, RSMO, defines "Pharmacy distributor" as follows:

(2) "Pharmacy distributor", any licensed pharmacy, as defined in § 338.210, engaged in the delivery or distribution off legend drugs to any other licensed pharmacy where such delivery or distribution constitutes at least five percent of the total gross sales of such pharmacy[.]

20. 4 CSR 220-2.090(2) describes the responsibilities of a pharmacist-in-charge and states, in pertinent part:

(2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:

...

(E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;

...

(V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items;

...

(W) Assure full compliance with all state and federal drug laws and rules[.]

...

(Z) Maintain compliance with all state and federal laws governing drug distributor activities and assure that appropriate licensure as a drug distributor is secured if lawful thresholds for unlicensed distributions are exceeded[.]

...

21. 4 CSR 220-2.400(7) governs quality control for compounding of pharmaceuticals and states, in pertinent part:

(7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

(A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:

...

(6) The identity of the source, lot number and the beyond-use date of each drug product ingredient, as well as in-house lot number and a beyond-use date for bulk compounded products

...

(B) Information related to and the methods of compounding shall be available upon request

...

22. 4 CSR 220-2.010(6) states, in pertinent part:

(6) Drugs and devices that are maintained as part of the pharmacy inventory or are being processed for dispensing or other distribution purposes must be physically separated at all times from articles, supplies or other drugs that are for employee personal use or that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances. Areas used for this type of drug storage must be clearly identified. Any prescription drugs that are present in a licensed pharmacy but are for the personal use of pharmacy personnel must be labeled in accordance with section 338.059, RSMo.

23. Cause exists for the Board to take disciplinary action against Licensee pursuant to § 338.055.2(5) because failure to ensure that the pharmacy had proper licensure for drug distributors, failure to comply with compounding standards, specifically those dealing with appropriate record keeping and labeling, failure to separate outdated drugs from the active inventory, and failure to keep outdated drugs from being dispensed constitutes incompetency, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of a pharmacist and a pharmacist-in-charge.

24. Cause exists for the Board to take disciplinary action against Licensee pursuant to § 338.055.2( 6) because failure to ensure proper licensure as a drug distributor, failure to comply with compounding standards, failure to separate outdated drugs, and dispensing outdated drugs constitute violations of both this chapter and regulations adopted pursuant to this chapter.

25. Cause exists for the Board to take disciplinary action against Licensee pursuant to § 338.055.2(13) because Licensee's failure to maintain an active inventory free of outdated drugs and dispensing outdated drugs violate the trust the public places in Licensee by virtue of its status as a state-licensed pharmacist that Licensee will safeguard the public by preventing outdated drugs from being dispensed.

26. Cause exists for the Board to take disciplinary action against Licensee pursuant to § 338.022.2(15) because failure to ensure that the pharmacy had proper licensure for drug distributors, failure to comply with compounding standards, specifically those dealing with appropriate record keeping and labeling, failure to separate outdated drugs from the active inventory, and failure to keep outdated drugs from being dispensed violates § 338.333, RSMo, 4 CSR 220-2.090(2)(Z), 4 CSR 220-2.400(7)(A)(6), 4 CSR 220-2.400(7)(B), 4 CSR 220-2.010(6), 4 CSR 220-2.090(2)(V), 4 CSR 220-2.090(2)(E) and (W).

#### Joint Agreed Disciplinary Order

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of § 621.045.3, RSMo 2000.

1. Licensee's pharmacist license, License No. 41012, is immediately placed on PROBATION for a period of two (2) years. The terms of the probation shall be:

A. Licensee shall keep the Board apprised of her current home and work addresses and telephone numbers. If at any time Licensee is employed by a

temporary employment agency or maintains employment that requires frequent daily or weekly changes of work locations she must provide the board with all scheduled places of employment in writing prior to any scheduled work time.

- B. Licensee shall pay all required fees for licensing to the Board and shall renew her license prior to October 31 of each licensing year.
- C. Licensee shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
- D. Licensee shall make herself available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Licensee will be notified and given sufficient time to arrange these meetings.
- E. Licensee's failure to comply with any condition fo discipline set forth herein constitutes a violation of this disciplinary agreement.
- F. The parties to this agreement understand that the Board of Pharmacy will maintain this agreement as an open record of the Board as provided in Chapters 338, 610, 620, RSMo.

- G. If, after disciplinary sanctions have been imposed, the licensee ceases to keep her Missouri license current, fails to keep the Board advised of her current place of employment and residence, or begins employment as a pharmacist or technician outside the state, such periods shall not be deemed or taken as any part of the time of discipline so imposed. Licensee may petition the board to seek a waiver for any portion of this requirement by making such a request in written form to the Board for its consideration. No exception will be made to this requirement without prior board approval.
- H. Licensee shall provide all current and future pharmacy and drug distributor employers and pharmacist/manger-in-charges a copy of this disciplinary agreement within five(5) business days of the effective date of discipline or the beginning date or each employment. If at any time Licensee is employed by a temporary employment agency she must provide each pharmacy and drug distributor employer and pharmacist/manger-in-charge a copy of this disciplinary agreement prior to or at the time of any scheduled work assignments.
- I. Licensee shall not serve as a preceptor for interns.
- J. Licensee shall not serve as a pharmacist in charge or in a supervisory capacity without prior approval of the Board.

- K. Licensee shall report to the Board, on a preprinted form supplied by the Board office, once every 6 months, beginning 6 months after this agreement becomes effective, stating truthfully whether or not she has complied with all terms and conditions of his disciplinary order.
- L. Licensee shall take and pass the Board's designated jurisprudence (law) examination.
1. Licensee may serve as a pharmacist in charge once Licensee passes the jurisprudence examination.
  2. Failure to obtain a passing score on the jurisprudence examination two times shall constitute a violation of the terms of Licensee's probation.
  3. Licensee shall contact the Board of Pharmacy office to request a current law packet and the required registration materials no less than ninety (90) days prior to the date Licensee desires to take the examination. Licensee shall complete the registration materials and submit them and the required fee to the Board office. Upon Licensee's receipt of an Authorization to Test (ATT), Licensee shall schedule the exam as instructed.
- M. Out of the required continuing education hours required for renewal of a license, Wilcox shall provide for 4 hours of continuing education in the area of pharmacy law.

1. The additional continuing education hours required must be "contact hours." "Contact hours" are defined as "in person" attendance at seminars, classes, programs, etc., and not correspondence courses. Contact hours may include courses participated in via computer or video links but only if the means of participation allows real-time, contemporaneous interaction between the presenter and Licensee.
2. Because license renewals are on a two-year cycle, if Licensee's discipline ends in a non-renewal year, Licensee shall submit the required additional continuing education to the Board office before the end of the disciplinary period. The continuing education hours required by law for renewal of Licensee's license shall be submitted with the renewal application.

2. The parties to this settlement agreement understand that the Board of Pharmacy will maintain this settlement agreement as an open and public record of the Board as provided in Chapters 338, 610, and 620, RSMo.

3. Upon the expiration of said discipline, Licensee's pharmacist license in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Licensee has violated any term or condition of this settlement agreement, the Board may, in its discretion, after an evidentiary



hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Licensee.

4. No order shall be entered by the Board pursuant to the preceding paragraph of this settlement agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

5. If the Board determines that Licensee has violated a term or condition of this settlement agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this settlement agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this settlement agreement during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this settlement agreement has occurred.

6. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

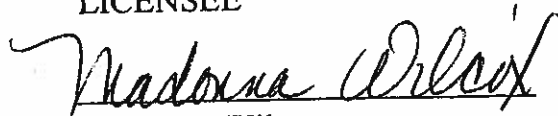
7. Licensee hereby waives and releases the Board, its members and any of its employees, agents or attorneys, including any former Board members, employees, agents and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to § 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this settlement agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this settlement agreement in that it survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion thereof void or unenforceable.

8. Licensee understands that she may, either at the time the settlement agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Licensee's license. If Licensee desires the Administrative Hearing Commission to review this Agreement, Licensee may submit her request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65101.

9. If Licensee requests review, this settlement agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the settlement agreement sets forth cause for disciplining Licensee's license. If Licensee does

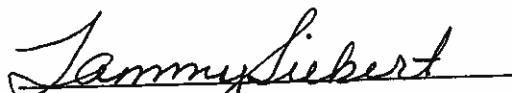
not request review by the Administrative Hearing Commission, the settlement agreement goes into effect 15 days after the document is signed by the Executive Director of the Board.

LICENSEE

  
Madonna Wilcox

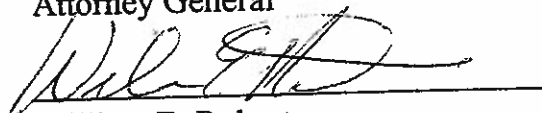
Date 10/9/06

BOARD

  
Tammy Siebert  
Executive Assistant  
State Board of Pharmacy

Date 10-23-06

JEREMIAH W. (JAY) NIXON  
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Attorneys for Board

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Zachary W. Bergan  
39 Hickory Lane  
Higganum, CT 06441  
NV Lic# 15889  
December 10, 2009

Nevada State Board of Pharmacy  
431 W. Plumb Lane  
Reno, NV 89509

Dear Nevada State Board of Pharmacy:

I am writing to request a reinstatement of my pharmacy license and an opportunity to come before the board January 13<sup>th</sup> or 14<sup>th</sup> 2010 in Las Vegas, Nevada. I currently reside in the state of Connecticut and have since October 2007. My license has been suspended in Nevada since April 2008 but I have not practiced since September 2007. Due to this suspension I am unable to transfer my license to Connecticut where I intend to resume practice.

While living in Nevada I developed a serious addiction to narcotics to deal with stress, depression, an unhappy marriage, the loss of a baby and isolation from my family and friends. I recognized before moving from Nevada that my life would have to change drastically in order to recover and live a full and happy life. When I returned to Connecticut two years ago my focus was on recovery and starting a new life. I intended to transfer my license to Connecticut as a piece of that recovery although I was unsure if I would return to practice again knowing I had serious addiction issues. In the time I have spent working on my recovery I have recognized that returning to practice and being a responsible pharmacist is an important goal of mine.

In July 2008 I completed 6 months of outpatient treatment for my addiction issues at the Rushford Center in Middletown, CT. I also attended Pharmacists Concerned for Pharmacists 12 step meetings. I have maintained sobriety for 2 years - since September 2<sup>nd</sup>, 2007 – and am committed to long term sobriety.

Currently, I am employed with FedEx Home Delivery in Wallingford, CT. Since leaving the state of Nevada in 2007 I have been employed outside the practice of pharmacy (see resume) with the exception of January until April 2008 when I was unemployed; attending treatment, meetings and anticipating my license being transferred to Connecticut. In late April 2008 my license was issued in the state of Connecticut post completion of the transfer process and after passing the state law exam. However, before being able to practice in Connecticut I was asked to relinquish the license because of the Nevada suspension.

My degree and career in pharmacy were an investment in my future and since losing my license I have not only had trouble finding fulfilling long term employment but I have also gone through a divorce, bankruptcy and lost my home. I have continued to look for work within the non-dispensing pharmacy field however there are very few opportunities for pharmacists outside of dispensing. In exploring other occupations I have gained the perspective that pharmacy is where I excel, helping others is what I am meant to do and what I have heavily invested myself in – educationally and personally. I find helping others and being a community resource to be fulfilling and challenging and that the work is rewarding, a sentiment I had lost in my addiction. I

now feel that I am at a point where returning to the field is a positive step in my recovery and an important step towards realizing healthy goals for my future.

Currently, I reside with my parents and continue to be accountable daily at work and at home for the positive changes in my life. I employ healthful methods for stress relief and conflict resolution. I am proud of my continued sobriety and am thankful for the support of my family and my friends.

In addition to my treatment and meetings I have become involved in the community – working for a local family owned farm and coaching soccer for 7-8 year olds at a local YMCA. I am also in a long term relationship with the intention of getting married, being a step-father to a 7 year old girl and starting our family in the near future. All of these ties; to my parents, my community and to my future wife are what make me certain that I am able to return to a pharmacy and maintain recovery that I have worked very hard for over the past few years.

My goal is to have my license reinstated and to practice in the state of Connecticut where I have a large support system of family and friends. I am ready to return to practice and I feel I am an asset to the pharmaceutical community in many aspects. My ability to communicate with patients and assist them was one of my favorite aspects of the job and my dedication to continued education and current pharmaceutical standards will be a benefit to any employer. I realize that I may need to participate in a monitoring program and be tested after regaining my license and I am willing to do whatever it takes to return to my profession.

Thank you for the opportunity to be considered for reinstatement as a licensed pharmacist. I look forward to the chance to meet you in person and discuss these issues in more depth. I sincerely appreciate the gravity of the decision and understand that patient safety and wellness are your foremost concern. I am ready, willing and able to communicate openly and address these challenges to become a successful caregiver again.

Sincerely,

Zachary W. Bergan.

# **Zachary Bergan**

39 Hickory Lane  
Higganum, CT  
06441  
H: 860-345-2676  
C: 775-781-8421  
zbergan@gmail.com

## **Employment History**

### ***Delivery Driver***

November 09 – Present 09 FedEx Home Delivery, Wallingford, CT

- Accurate and timely delivery of packages on the Madison / Guilford route
- Safe driving with a company vehicle
- Responsible for valuable cargo and documents

### ***Salvage Technician / Marine Construction***

July 08 – August 09 Associated Marine Salvage Inc, Miami, FL

- Heavy Equipment operation – 4WD forklift, excavator
- General Marine Construction
- Rigging
- Boat Operation and Dive Tending / Diving
- Work was 100% travel based – home base was Connecticut

### ***Landscape Technician***

April 08 – July 08 Landscape Specialties, Centerbrook, CT

- General landscaping – lawns, trees, rock walkways
- Landscape construction – grading / leveling
- Customer service driven with an emphasis on custom landscaping for new or complete landscape designs

### ***Tree Farm Technician***

October 07 – April 08 Peaceful Hill Tree Farm, East Hampton, CT

- Cutting and Pruning of Trees
- Mowing and maintenance of property

### ***Pharmacist – Retail and Hospital***

Sept 02 – October 07 Carson City, NV

- Licensed pharmacist in NV
- Management responsibilities – scheduling, inventory, ordering, cash reconciliation, opening and closing of pharmacy
- Customer service – patient counseling, customer satisfaction, fast paced environment with 100% accuracy required

## **Education**

1996 - 2002 University of Connecticut, Storrs, CT

Doctorate of Pharmacy

## **Summary of Qualifications**

- Ability to work in a fast paced high pressure environment without supervision. Includes skills to problem solve, review situations and feedback to create long term solutions.
- Communication skills that allow policies, information, and instructions to be clearly conveyed.
- Proven track record of excellent customer service combined with a real desire to provide employer and consumers with results.
- A positive attitude and work ethic that provides co-workers and employers with a sense of security and confidence.

39 Hickory Lane (775) 781-8421  
Higganum, CT 06441 zbergan@gmail.com

# Zachary W. Bergan, Pharm D.

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## Experience

Oct 06-June 2007 Carson Valley Medical Center Gardnerville, NV  
**Staff / Clinical pharmacist**

- Preparation of IV products for medical floor and infusion center  
-Chemo, antibiotics, fluids, TPN
- Antibiotic monitoring ( Vanco/Gent)
- Educate medical staff on drug therapy
- Prepare and maintain Code (crash) carts
- Maintain satellite med rooms
- Perform patient counseling

2002- Nov 2006 Walgreens Drug Carson City, NV  
**Staff Pharmacist**

- Prescription verification and preparation (avg 300 rx/days)
- Extensive patient counseling (Rx and OTC)
- Drive thru pharmacy

2004-2006 Medcare Pharmacy Carson City, NV  
**Relief Pharmacist**

- Verification and counseling duties
- Verify blister packs for long term care facilities
- Rx compounding

June 2007- Oct 07 Humboldt General Hospital Winnemucca, NV  
**Relief Pharmacist**

- Preparation and distribution of IV products
- MD consultation on IV antibiotic therapy
- Medcart filling for nursing stations and long term care floor
- Worked with surgery and obstetrics teams



June 2007 – Oct 07 Westhills Psychiatric Hospital Reno, NV

**Relief Pharmacist**

- Provided services for Adult addiction services as well as pediatric psych floor.
- Consultation with MD's on appropriateness of dosages in pediatric patients
- Prepared med boxes to be sent to offsite facilities

June 2007 – Oct 07 Rite Aid Pharmacy Fallon , NV

**Relief Pharmacist**

- Relief staffing for chain retail
- Drive thru experience

June 2007 – Oct 07 Longs Pharmacy Reno, NV

**Relief Pharmacist**

- Relief staffing for retail chain

June 2007 – Oct 07 Smith's Food and Drug Dayton, NV

**Relief Pharmacist**

- Relief staffing for retail chain

Education	1998-2002	University of Connecticut	Storrs, CT
	<ul style="list-style-type: none"><li>▪ BS pharmacy sciences (2001)</li><li>▪ Pharm D. (2002)</li><li>▪ Research in new drug synthesis ( SAR)</li><li>▪ Internships in critical care (Yale), Oncology (Yale), Geriatrics, General medicine (Hartford hospital, UCONN health center)</li></ul>		
Other Experience	2001	PCCA	Houston, TX
	<ul style="list-style-type: none"><li>▪ Completed 5 day certification course in Rx compounding</li></ul>		
Profesional Groups	Kappa Psi member since 1999		

To Whom It May Concern,

I am writing this letter in wholehearted support of the character and integrity of Zachary William Bergan, Pharm D. as he seeks reinstatement from the Nevada Board of Pharmacy. I have known Mr. Bergan for almost 28 years, having attended grammar and high school with him since kindergarten. While we could never be confused with being inseparable, Zach and I have been steadfast friends from almost the beginning of our acquaintance until this very day. It has been a friendship that distance or time has never deteriorated. As often happens between friends, we took different paths after high school – he to play baseball and study pharmacy while I pursued a career in marine science. Despite the fact that we would go months and occasionally a year without seeing one another, our reunions were as if we had seen each other the day before. Our friendship never missed a beat.

The reason for this effortlessly strong friendship lies largely due to Zach's loyal nature and kind heart. He may one of the most genuine and caring people I have ever met. Reasonable to a fault, his non-judgmental and intuitive perspective has settled many and argument and mended many a fence. For the balance of our relationship I have considered Zach as one of the more exceptional human beings I have ever met. Given this, you could understand my concern when Zach approached me about his professional mistakes and the ramifications they have had on his life.

This fall Zach shared with me that he had not been practicing pharmacy for some time due to an abuse problem he had faced when in Nevada. He had, in the interim, been working in other fields, but now truly wished to repair the professional damage he had done and begin his career anew. He stated that he had completely defeated his substance problem shortly after the suspension of his license in Nevada, but needed to step away from the profession for a while. I believe that Zach has corrected the behavior that got him into trouble, a belief based both on personal observation and my knowledge of Zach's forthright and honest character. With that behind him, I feel that Zach is ready to again begin doing what I feel he is truly meant to do – help people.

People should not be defined by their mistakes, but rather how they use the lessons they teach to make themselves better people. I am completely confident that Zach Bergan has learned from his mistakes and has defeated the problems that have impeded his professional progress. I also believe that these life lessons will make Zach an even more valuable asset to both his community and the pharmacological community as a whole. Please accept this letter in ironclad support of the character, integrity and honesty of Zachary William Bergan, Pharm D.

Thank You.

Ian Gibson  
Marine Science Instructor  
Old Saybrook High School  
Old Saybrook, CT

To whom it may concern,

It is with great pleasure that I am writing this letter of recommendation in support of Zack Bergan. I have known Zack for over 25 years as a friend of my son. I was always impressed with his polite manner, intelligence and work ethic. I was happy when Zack chose pharmacy as a career since that has been my profession for over 35 years. I lost personal contact with Zack when he moved to Nevada but have reconnected with him this past year after his relocation back to Connecticut.

In addition to being a community pharmacist I am also a vegetable farmer. This past year Zack has worked for me on the farm and once again I have enjoyed his company. It was as a friend and employer that Zack shared with me why he was no longer practicing pharmacy. He openly shared with me his mistakes and the professional offences he committed. Zack is open and honest about his regret and shows a steadfast willingness to correct his mistakes and a strong determination to stay on his path of recovery. As his employer, I have had no reason not to believe his word or intentions. He is always consistent, on time, and works hard to get the job done while always being a pleasure to be around.

It is with confidence in Zack's character, honesty and desire for self-improvement that I recommend Zack for reinstatement into the pharmacy profession. His humility and desire to help people will just make him a better pharmacist. Considering the serious nature of this reinstatement, I am available for further discussion if necessary. Please feel free to contact me at 860-345-3183.

Thank You,

Melissa Gibson R.P.h.

2. On August 5, 2007, Mr. Bergan was arrested for failing to maintain a travel lane, DUI drugs, and possession of drugs without a prescription. The drugs Mr. Bergan was found to possess without a prescription were loose Didrex tablets found on his person at the time of arrest.

3. When Longs #125 was notified of Mr. Bergan's arrest, it did an audit of its inventory and found that an entire stock bottle of Didrex tablets was missing. Mr. Bergan had worked at Longs #125 on August 3 and 4, the two days before his arrest.

4. On August 19, 2007, Mr. Bergan was employed at HGH and was being trained by pharmacy manager David Simsek. On September 8, 2007, a pharmaceutical technician at HGH reported to Mr. Simsek that she had notice that 40 tablets of generic Norco were missing from the controlled substances safe. Mr. Simsek could not find any accounting errors and decided to check in the safe that held outdates. Mr. Simsek found 30 additional tablets of generic Norco missing from the safe. Mr. Simsek thereafter did a complete inventory of the outdates and found 40 Oxycodone 5 mg. tablets and seven morphine 15 mg. tablets missing. Mr. Simsek's practice was to prepare a DEA form 41 for the outdated drugs and to hold them separately until the Board's inspector came to Winnemucca so that the Board's inspector could destroy them.

5. Mr. Simsek had done a complete controlled substances inventory in July 2007 and had found everything to be balanced. On September 9, 2007, Mr. Simsek took an inventory of HGH's controlled substances and the inventory revealed that a total of 100 Oxycontin 5 mg. tablets, 18 carisoprodol 350 mg. tablets, and 7 alprazolam 1 mg. tablets were missing. Mr. Simsek reviewed all of HGH's records of purchased, chart orders, expired drugs, floor stock, and invoices and was not able to account for the missing drugs. The only difference in the practice of the pharmacy at HGH between the July and September inventories was the employment of Mr. Bergan.

6. Mr. Simsek was gone from the pharmacy from September 16 through 20, 2007, leaving Mr. Bergan as the pharmacist in charge. When Mr. Simsek returned to

HGH, his pharmaceutical technicians reported that Mr. Bergan had engaged in unusual behavior such as arriving late for work, long lunch hours, extremely long bathroom trips, and numerous trips outside the HGH building while on shift. Mr. Bergan also suffered from profuse sweating during the five days.

7. Mr. Simsek took another inventory when he returned on September 21, 2007. The inventory revealed an additional shortage of 190 Oxycodone 5 mg. tablets, two temazepam 30 mg. capsules, and three carisoprodol 350 mg. tablets.

8. The total controlled substances missing from HGH attributable to Mr. Bergan's unlawful removal were:

<b>CONTROLLED SUBSTANCE</b>	<b>MISSING DOSAGE UNITS</b>
Norco	70
Oxycodone 5 mg.	230
Morphine 15 mg.	7
Oxycontin 5 mg.	100
Carisoprodol 350 mg.	21
Alprazolam 1 mg.	7
Temazepam 30 mg.	2

9. Mr. Bergan filed an Answer and Notice of Defense on February 24, 2008 that was received by the Board's office on February 28, 2008. In his Answer, Mr. Bergan did not deny any of the accusations made in the Notice of Intended Action and Accusation in this matter. Mr. Bergan also indicated that the estimates of the amount of controlled substances noted in the Notice of Intended Action and Accusation attributed to him seemed accurate. Mr. Bergan also indicated that he had not worked in a pharmacy since he left HGH and that he was attending substance abuse counseling and 12-step meetings (presumably in Connecticut, where he had moved after leaving HGH).

### **CONCLUSIONS OF LAW**

1. The Board has jurisdiction over this matter because Mr. Bergan is a pharmacist licensed by the Board.

2. In removing controlled substances from his employing pharmacies, namely Didrex, hydrocodone, oxycodone, morphine, Oxycontin, carisoprodol, alprazolam, and temazepam, without lawful orders therefore, Mr. Bergan violated NRS 453.336(1) and 639.210(4) and (12) and NAC 639.945(1)(h) and (i).

### **ORDER**

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

1. Mr. Bergan's pharmacist's license (#15889) is revoked. Mr. Bergan may not be employed in any business registered by the Board in any capacity unless and until his pharmacist's license has been reinstated.

2. Mr. Bergan shall return to the Board's Reno office his wall certificate and wallet card within 10 days of his receipt of this Order. His failure to do so will result in a fine of \$1,000 per day until the documents are received by the Board office.

Signed and effective this 3<sup>rd</sup> day of April, 2008.



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Barry Boudreaux, President  
Nevada State Board of Pharmacy

Blank



Alexis Gillmore  
3360 Shady Lane  
Green Bay, WI 54313  
December 8, 2009

Nevada Board of Pharmacy  
431 W. Plumb Lane  
Reno, NV 89509

Dear Nevada Board of Pharmacy:

I am writing to you to provide a character reference for Zachary W. Bergan.

I am pleased to recommend Zach to you for license reinstatement. I have known Zach for a little over 2 years. I met him shortly after he returned to Connecticut from Nevada in 2007.

In that time I have seen Zach go through a lot of personal changes; outpatient treatment for his addiction, bankruptcy, recovery from divorce and personal loss as well as taking responsibility for the personal and professional decisions that he made. I can say with absolute certainty that there are very few people that could have handled these things with such grace and humility. Even in the midst of losing everything Zach maintained his sobriety and turned his situation into a forum for helping others.

I believe that the character qualities that Zach shows are responsibility, integrity, humility, commitment, compassion and wisdom. There has not been a day in which Zach has strayed from his goals or become dragged down emotionally by the events of his past. He, at every turn, has remained positive and focused on his future. He has taken full responsibility and charted a new course for himself while keeping in mind the issues that he needs to work on and the character qualities that will bring him success. In learning about himself and his addiction Zach has become a leader within our circle of peers; expressing openly how to find better ways to deal with stress, loss and work on recovery. This level of openness and willingness to help others has brought our friends, family and our community closer. His compassionate nature and his gentle wisdom provide people with the opportunity to be candid with him and connect with him on a personal level even if he has only known them a short time. An example of this happened this fall with some family friends that had lost their son Brandon to brain cancer. The father, Jerry, doesn't speak about what happened to their son but within 15 minutes of meeting Zach was speaking openly about his son dying and how it affected him and his family. It was touching to see a man open up about his personal pain and to know that Zach, by listening compassionately, was helping Jerry to heal his wounds. This example is just one account of how Zach touches people and how his character shines through in every meeting.

Zach came into my life as a friend first and has become a committed partner in the past year. He and I are working to build a life together that includes marriage and a blended family with my 7 year old daughter. In seeing the husband that he will be and the father that he already is to my daughter I cannot help but simply be grateful that he has come into our lives. A clear example of this happened this fall while Zach was coaching my daughter's soccer team through the YMCA.

The kids enjoyed him on and off the field. They connected with him and listened to him from the first five minutes that he spoke. He was on their level and made sure that every player was respected and given a chance to play. The kids would run up in the morning and be happy to play for him; not because the soccer games were competitive or because their parents made them show up but because they knew that they would get to spend time with Zach. Another example of this is his relationship with my daughter Emma. Zach and Emma have a connection that makes me proud. He has come into our lives and has not shied away from the responsibilities of raising a girl that had no experience with a father in her life. Although we have to live in separate places (as of this fall) he has made a commitment to her; from school to after school activities and her spiritual growth. Zach has taught her to throw a baseball, helps her with her homework, reads to her at night before bed, involves her in outdoor games and activities, has taken care of her when she was sick, and is always available to give her encouragement, help and love. These things may seem simple but it takes a man of integrity to step in as a positive role model to children and work hard at being a father.

Zach and I both are aware of the challenges that are in front of him. Zach has planned short term and long term for the opportunity to return to pharmacy and I am confident that he is ready. Zach has worked hard to be able to manage his issues and to be a positive community resource and role model. I respectfully ask you to give him a chance to become a provider for our family and more importantly to be professionally fulfilled.

Thank you for your time reviewing this letter. Please feel free to contact me at any time with questions. If Zach is given the opportunity to come before the Board in January I have the intention of being there with him and would certainly be able to answer any questions or discuss these topics further in person.

Best Regards and Happy Holidays,

Alexis Gillmore  
[alexisgillmore@gmail.com](mailto:alexisgillmore@gmail.com)  
920-434-5495

To: The Nevada State Board of Pharmacy  
Character Reference: Zachary William Bergan

I have been acquainted with Mr. Bergan for almost a year. During this period Mr. Bergan was a guest in my home for several months. During this time Mr. Bergan assumed the role as part of our family taking upon himself responsibilities for household duties and contributing to the family without any expectation that he do so.

Mr. Bergan was very pleasant to be around and demonstrated a quick wit and welcome sense of humor. He dedicated himself to contribute to the family and the community as demonstrated by him agreeing to coach my granddaughter's soccer team. He proved to be an excellent role model for the children and helped them understand how to balance winning and losing with the more important aspects of sportsmanship.

Over the duration of the relationship Mr. Bergan has proven to be very responsible and diligent. In several discussions during this time, Mr. Bergan expressed deep concern for his previous indiscretions and was both contrite for his failures and determined to regain the trust and respect of his peers in his profession. It is my belief, he was being honest and sincere in this desire.

While a guest in my home Mr. Bergan maintained a sober demeanor though my family normally has wine and beer in the refrigerator, and it is very common for my wife and I to have wine in the evening with our meal. I do not recall a single instance where Mr. Bergan had more than a social drink and on most occasions declined to have a drink at all.

It was clear to me that Mr. Bergan has solid core values and a true desire to serve others through his chosen career. His continued interest in returning to pharmaceutical work is evidence as one speaks with Mr. Bergan. Consistently as he speaks pride is expressed in having been able to help others through his work and deep remorse is often voiced in regard to the mistakes he has made in the past.

I would highly recommend Mr. Bergan to anyone as a person of good moral character and someone who understands the seriousness of the challenge ahead and is committed to meeting that challenge. In this regard, I would ask you to please consider Mr. Bergan's request for reinstatement positively.

Thomas K. Gillmore  
Director of Market Research & Strategy  
Special Hazards Group  
Tyco Fire Suppression & Building Products  
1-920-434-5495 Home  
1-920-562-4084 Cell  
tgillmore@gmail.com

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**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.

New Pharmacy ☒ Ownership Change ☐ Name Change ☐ Location Change ☐  
(Please provide current license number if making changes: PH \_\_\_\_\_)

**GENERAL INFORMATION**

Pharmacy Name: Altius Healthcare  
Physical Address: 1151 Iron Springs Road, Suite G  
Mailing Address: 1151 Iron Springs Road, Suite D  
City: Prescott State: AZ Zip Code: 86305  
Telephone Number: 928-708-0025 Fax Number: 928-708-0288  
Toll Free Number: 1-800-531-2469  
E-mail: knestrick@altiusaz.com Website: AltiusAZ.com  
Managing Pharmacist: Kevin Nestrick License Number: 5006183

**Hours of Operation:**

Monday thru Friday 8 am 5 pm Saturday — am — pm  
Sunday — am — pm 24 Hours —

**TYPE OF PHARMACY**

**SERVICES PROVIDED**

- ☐ Retail
- ☐ Hospital (# beds \_\_\_\_\_)
- ☐ Internet
- ☐ Nuclear
- ☒ Out of State
- ☐ Ambulatory Surgery Center

- ☐ Off-site Cognitive Services
- ☒ Parenteral
- ☒ Parenteral (outpatient)
- ☐ Outpatient/Discharge
- ☐ Mail Service
- ☐ Long Term Care

**Board Use Only**

Received: \_\_\_\_\_ Check Number: 621 Amount: 500.00

## OWNERSHIP IS A CORPORATION

State of Incorporation: Arizona

Parent Company if any: \_\_\_\_\_

Corporation Name: Prescott I.V. Care Inc.

Mailing Address: 1151 Iron Springs Rd, Suite D

City: Prescott State: AZ Zip: 86305

Telephone: 928-708-0025 Fax: 928-350-4276

License Contact Person: Kevin Nestrick

Professional Compliance Contact Person: Kevin Nestrick

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. <u>Kevin Nestrick RPH</u> | %: <u>100</u> |
| 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:

\_\_\_\_\_  
\_\_\_\_\_

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, officer(s) 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)? Yes ☐ No ☒
- 2) Has the firm or any owner(s), shareholder(s) with at least 10% interest, officer(s) or director(s) thereof, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the firm or any owner(s), shareholder(s) with at least 10% interest, officer(s) or director(s) thereof, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the firm or any owner(s), shareholder(s) with at least 10% interest, officer(s) 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? Yes ☐ No ☒
- 5) Has the firm or any owner(s), shareholder(s) with at least 10% interest, officer(s) or director(s) thereof, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

Attached 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.

P. Kevin Nestrick

Signature of owner or executive officer

12-14-09

Date

P. KEVIN NESTRICK Chief Executive Officer

Print or Type name and title

Arizona State Board of Pharmacy

1992

**Complaint:**

Board action against Kevin Nestruck for non compliance with C Stamp requirements at IV pharmacy and one retail location (ink stamps were dry) on two consecutive inspections, non-compliance with equipment requirements (no metal spatula at IV Pharmacy) and non-compliance with pharmacist consultation requirement by employee pharmacist. All items were at Nestruck Pharmacy (retail locations) and Option Care IV Pharmacy located in Bullhead City, AZ, owned by Nestruck Pharmacy, Inc. and Option Care (also owned by Nestruck). Operations at these locations ended on May 1, 2009 when operations were sold.

Note: No other "complaints" have been filed against Nestruck or his owned operations. Current operations at Altius Healthcare are 100% infusion pharmacy services. No complaint has ever been filed at this operation. This pharmacy has been accredited since 1991 by JCAHO and ACHC. Nestruck has been owner of this pharmacy since its inception in August 1990.

**Actions resulting from Complaint:**

Nestruck's personal license was fined as owner of the pharmacies for failure to ensure compliance of these requirements at owned operations and for ensuring employee (Pharmacist in Charge) compliance. No revocation or suspension was imposed. Nestruck was not the Pharmacist In Charge at any of these locations, but the complaint was filed against Nestruck as "owner".

Fine paid. No other actions have ever been filed against K Nestruck or any staff pharmacist employed by Altius Healthcare in Prescott, AZ

Questions or concerns regarding these events can be directed to me at 928-708-0025 or by email at [knestruck@altiusaz.com](mailto:knestruck@altiusaz.com) or by mail at Altius Healthcare, 1151 Iron Springs Rd, Prescott, AZ 86305.



Kevin Nestruck, Pharmacist/owner  
AZ pharmacist license S006183.

Prescott  
(Central Office)  
1151 Iron Springs Rd.

Suite D  
928.708.0025  
fax 928.708.0288

Flagstaff  
928.233.6540  
fax 928.233.6542

Show Low  
928.532.8149  
fax 928.532.8160

Payson  
928.596.6540  
fax 928.596.6542

Phoenix  
602.344.6540  
fax 602.344.6542

Casa Grande  
520.381.1998  
fax 520.381.1999

Tucson  
520.795.0111  
fax 520.795.2332

Yuma  
928.373.0101  
fax 928.373.9896



CORPORATE STATEMENT OF RESPONSIBILITY  
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, P. Kevin Nestrick

Corporate Officer of Prescott IV Care Inc, d/b/a ALTius Healthcare

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.

P. Kevin Nestrick  
Signature

12-7-09  
Date

**NEVADA STATE BOARD OF PHARMACY**  
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

**PHARMACY LICENSE VERIFICATION**

Name: Prescott IV Care, dba Altius Healthcare  
Address: 1151 Iron Springs Rd, Ste G  
City: Prescott State: AZ Zip: 86305

I hereby authorize the Arizona Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant P. Kevin Martin

THIS FORM MUST BE FORWARDED TO THE HOME STATE  
LICENSING AGENCY FOR COMPLETION  
DO NOT WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
<u>Y002154</u>	<u>Open - Good Standing</u>	<u>10-10-90</u>	<u>10-31-10</u>

Has this license been encumbered in any way? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Type of Encumbrance: (if any) <input type="checkbox"/> Revoked <input type="checkbox"/> Surrendered <input type="checkbox"/> Limited <input type="checkbox"/> Suspended <input type="checkbox"/> Restricted <input type="checkbox"/> Probation Please attach copies of any pertinent legal documents
---	---

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain) ☐ Yes ☒ No

Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain) ☐ Yes ☒ No

Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain) ☐ Yes ☒ No

Has applicant met all licensing requirements of your state? (If no, please explain) ☒ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal
<u>Cynthia Hunter</u>	<u>Executive Secy</u>	<u>AZ</u>	<u>12-16-09</u>	

APR 22 2009

San Antonio

San Antonio

# PREPARING FOR REGULATORY INSPECTORS

LARRY L. PINSON, PHARM. D.  
EXECUTIVE SECRETARY  
NEVADA STATE BOARD OF  
PHARMACY



# Learning Objectives

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## **Upon completion of this program, participants will be able to:**

- Discuss the preparation required for a Board of Pharmacy inspection, including record keeping.
- Discuss the management of deficiencies that may result from an inspection.
- Describe the legal rights provided to a pharmacy, wholesale distributor, or manufacturer when under investigation.
- Explain how licensed facilities should address an inspection performed by a State Board of Pharmacy, DEA or FDA.
- List the legal options for those accused of being in violation of state and/or federal laws

# **Medication Safety Practices**

**Your Success RX Consulting  
Katie Johnson, RPh, MA**

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IN THE SUPREME COURT OF THE STATE OF NEVADA

LEILA-JADE G. SANCHEZ AND TAYLOR  
N. SANCHEZ, MINORS, BY AND  
THROUGH JOSETTE SANCHEZ, THEIR  
GUARDIAN; JOSETTE SANCHEZ, AN  
INDIVIDUAL; THERESE CRUZ-BLAS AND  
DELBERT M. BLAS, AS CO-SPECIAL  
ADMINISTRATORS OF THE ESTATE OF  
GREGORY SANCHEZ, JR., DECEASED;  
ROBERT MARTINEZ, AN INDIVIDUAL;  
AND MICHELLE MARTINEZ, AN  
INDIVIDUAL,

Appellants,

vs.

WAL-MART STORES, INC., A FOREIGN  
CORPORATION; LONGS DRUG STORES  
CO., A FOREIGN CORPORATION;  
WALGREEN CO., A FOREIGN  
CORPORATION; CVS PHARMACY, INC., A  
FOREIGN CORPORATION; RITE-AID, A  
FOREIGN CORPORATION; ALBERTSON'S,  
INC., D/B/A SAV-ON PHARMACY, A  
FOREIGN CORPORATION; AND LAM'S  
PHARMACY, INC., A NEVADA  
CORPORATION,

Respondents.

No. 47851

**FILED**

DEC 24 2009

TRACIE K. LINDEMAN  
CLERK OF SUPREME COURT  
BY *[Signature]*  
CHIEF DEPUTY CLERK

Appeal from a district court order, certified as final under  
NRCP 54(b), dismissing appellants' complaint against respondents in a  
wrongful death and personal injury action. Eighth Judicial District Court,  
Clark County; Douglas W. Herndon, Judge.

Affirmed.

Marquis & Aurbach and Phillip S. Aurbach and Micah S. Echols, Las Vegas; Patti, Sgro & Lewis and Stephen K. Lewis, Las Vegas; Beckley Singleton, Chtd., and Daniel F. Polsenberg, Las Vegas, for Appellants.

Phillips, Spallas & Angstadt, LLC, and John W. Kirk, Las Vegas; Shook, Hardy & Bacon, LLP, and Frank C. Rothrock, Irvine, California, for Respondent Wal-Mart Stores, Inc.

Hutchison & Steffen, LLC, and Michael K. Wall and L. Kristopher Rath, Las Vegas, for Respondent Longs Drug Stores.

Backus Carranza and Leland Eugene Backus and Edgar Carranza, Las Vegas, for Respondent Walgreen Company.

Pyatt Silvestri & Hanlon and Carrie McCrea Hanlon, Las Vegas, for Respondent CVS Pharmacy, Inc.

Laxalt & Nomura and Lon A. Burke, Las Vegas; Kelly, Herlihy & Klein LLP and Jonathan Allan Klein, San Francisco, California, for Respondent Rite-Aid Corporation.

Thorndal, Armstrong, Delk, Balkenbush & Eisinger and Brian K. Terry and Christopher J. Curtis, Las Vegas, for Respondents Albertson's, Inc., and Lam's Pharmacy, Inc.

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BEFORE THE COURT EN BANC.

OPINION

By the Court, HARDESTY, C.J.:

This appeal raises issues concerning whether a pharmacy owes a duty of care to unidentified third parties who were injured by a pharmacy customer who was driving while under the influence of controlled prescription drugs. In addressing this appeal, we consider two



main arguments: (1) whether, under common-law principles, pharmacies have a duty to act to prevent a pharmacy customer from injuring members of the general public; and (2) whether Nevada's pharmacy statutory and regulatory laws allow third parties to maintain a negligence per se claim for alleged violations concerning dispensation of prescription drugs and maintenance of customers' records.

The underlying matter arose after a pharmacy customer, while driving under the influence of prescription drugs, allegedly caused an automobile accident resulting in one person's death and severe injuries to another. Appellants filed a wrongful death and personal injury complaint against, among others, respondent pharmacies that filled multiple prescriptions for the woman driving the car. The appellants claimed that because the pharmacies had knowledge of the woman's prescription-filling activities, the pharmacies owed appellants a duty of care to not fill the woman's prescriptions. The pharmacies filed a motion to dismiss the action, which the district court granted after finding that the pharmacies did not owe appellants a statutory duty of care, and thus, that appellants' claims failed to state a valid cause of action.

We conclude that pharmacies do not owe a duty of care to unidentifiable third parties. Moreover, Nevada's pharmacy statutes and regulations concerning prescription drug dispensation and customer recordkeeping maintenance are not intended to protect the general public from the type of injury sustained in this case, and thus, do not support the appellants' negligence per se claim. We therefore affirm.

#### RELEVANT FACTS AND PROCEDURAL HISTORY

On June 4, 2004, while driving on U.S. Highway 95 in Las Vegas, Gregory Sanchez, Jr., stopped on the side of the road to fix a flat tire. Appellant Robert Martinez, Sanchez's co-worker, arrived at the scene

to assist Sanchez. While Martinez and Sanchez were transferring items from Sanchez's vehicle into Martinez's vehicle, they were struck by defendant Patricia Copening's vehicle.<sup>1</sup> As a result of the collision, Sanchez died and Martinez was seriously injured. Copening was arrested for driving under the influence of controlled substances.

Appellants, Sanchez's minor daughters, his widow, and the personal representatives of his estate, and Martinez and his wife, filed a wrongful death and personal injury complaint against Copening, two medical doctors, and a medical association. Through discovery, appellants learned that in June 2003, the Prescription Controlled Substance Abuse Prevention Task Force sent a letter to the pharmacies that had dispensed to, and physicians who had written prescriptions for, Copening, concerning Copening's prescription-filling activities. The letter informed the pharmacies and physicians that from May 2002 to May 2003, Copening had obtained approximately 4,500 hydrocodone pills at 13 different pharmacies. Based on the Task Force letter, appellants moved the district court and were granted leave to file a second amended complaint to add the following defendants to the action: Wal-Mart Stores, Inc.; Longs Drug Stores Co.; Walgreen Co.; CVS Pharmacy, Inc.; Rite-Aid; Albertson's Inc., d/b/a Sav-on Pharmacy; and Lam's Pharmacy, Inc.

As to the pharmacies, the second amended complaint alleged that Copening was under the influence of controlled substances when the accident occurred and that the pharmacies had filled Copening's

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<sup>1</sup>Copening is not a party to this appeal. Appellants' claims against her remain pending in the district court, and we make no observations regarding the substantive legal issues pending in the underlying action.

prescriptions after they had received a Task Force letter informing them of her prescription-drug activities. The complaint further asserted that after receiving the Task Force letter, the pharmacies continued providing Copening with the controlled substances that she used before the accident. The complaint did not allege any irregularities on the face of the prescriptions themselves. Nor did the complaint allege that the prescriptions presented by Copening to the pharmacies were filled by the pharmacies in violation of the prescriptions' language, were fraudulent or forged, or involved dosages that, individually and if taken as directed, were potentially harmful to Copening's health.

The pharmacies answered the complaint and asserted, as an affirmative defense, that appellants' second amended complaint failed to state a claim upon which relief could be granted. Thereafter, the pharmacies moved the district court to dismiss the claims asserted against them in appellants' second amended complaint on the basis that no duty was owed to appellants. The pharmacies subsequently moved the district court for summary judgment. Appellants opposed the motions.

At the hearing on the pharmacies' motions, the district court stated that no statute imposed a duty on the pharmacies to take action after receiving the Task Force letter. The district court further stated that absent a legislative duty, the case was governed by Nevada's dram-shop cases and that there appeared to be no material difference between a bartender providing a customer alcohol and a pharmacist filling a customer's prescription, and therefore, proximate cause did not exist.<sup>2</sup>

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<sup>2</sup>We note that the district court's reliance on Nevada's dram-shop cases was unnecessary. In particular, it appears that after concluding  
*continued on next page . . .*

Thereafter, the district court entered a summary order that granted the pharmacies' motions to dismiss under NRCP 12(b)(5) and denied as moot the pharmacies' summary judgment motions. The court subsequently certified its order as final under NRCP 54(b). This appeal followed.

### DISCUSSION

The issues presented in this appeal raise two long-standing negligence principles. First, we consider whether pharmacies owe a duty of care to unidentified third parties injured by a pharmacy customer or whether public policy creates a duty of care for pharmacies, which when breached, supports a common-law negligence claim. Second, we decide if Nevada's pharmacy statutes and regulations create a statutory duty to support appellants' negligence per se claim against the pharmacies.

#### Standard of review

A district court order granting an NRCP 12(b)(5) motion to dismiss is subject to rigorous appellate review. Lubin v. Kunin, 117 Nev. 107, 110-11, 17 P.3d 422, 425 (2001). Similar to the trial court, this court accepts the plaintiffs' factual allegations as true, but the allegations must be legally sufficient to constitute the elements of the claim asserted. Malfabon v. Garcia, 111 Nev. 793, 796, 898 P.2d 107, 108 (1995). In

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*... continued*

that there was no legislative mandate imposing a legal duty, the district court next considered whether proximate cause existed. An analysis of proximate cause, however, was not required, as the district court correctly noted the absence of a legal duty imposed on respondents in favor of appellants. Accordingly, we determine that we need not consider the proximate cause element in this matter. See Rosenstein v. Steele, 103 Nev. 571, 575, 747 P.2d 230, 233 (1987) (noting that this court will affirm a district court's order if the district court reached the correct result, even for the wrong reason).

reviewing the district court's dismissal order, every reasonable inference is drawn in the plaintiffs' favor. Id. Accordingly, to prevail in this appeal, the appellants must demonstrate that a duty of care was owed to them by the pharmacies, which is a question of law that we review de novo. Turner v. Mandalay Sports Entm't, 124 Nev. \_\_\_, \_\_\_, \_\_\_, 180 P.3d 1172, 1175, 1177 (2008).

Pharmacies do not have a duty to act to prevent a pharmacy customer from injuring an unidentified third party

Appellants argue that the district court improperly dismissed their common-law negligence claims for two reasons. First, appellants contend that the pharmacies had a duty to prevent harm to appellants because Copening was a customer to whom the pharmacies continuously dispensed drugs, and the pharmacies had notice from the Task Force letter that Copening was a potential drug abuser. Second, appellants assert that NRS 453.1545 establishes a public policy duty to protect the general public, including appellants. The pharmacies counter that no special relationship exists between the pharmacies and appellants, and that no public policy duty is created by NRS 453.1545's enactment. We agree with the pharmacies' position that the district court properly declined to impose a duty on the pharmacies for the appellants' benefit.

No special relationship exists to justify imposing a duty on pharmacies in favor of third parties

It is well established that to prevail on a negligence claim, a plaintiff must establish four elements: (1) the existence of a duty of care, (2) breach of that duty, (3) legal causation, and (4) damages. Turner, 124 Nev. at \_\_\_, 180 P.3d at 1175. With regard to the duty element, under common-law principles, no duty is owed to control the dangerous conduct of another or to warn others of the dangerous conduct. See Mangeris v.

Gordon, 94 Nev. 400, 402, 580 P.2d 481, 483 (1978). An exception to this general rule arises, however, and an affirmative duty to aid others is recognized when (1) a special relationship exists between the parties or between the defendant and the identifiable victim, and (2) the harm created by the defendant's conduct is foreseeable. Lee v. GNLV Corp., 117 Nev. 291, 295, 22 P.3d 209, 212 (2001); Elko Enterprises v. Broyles, 105 Nev. 562, 565-66, 779 P.2d 961, 964 (1989); Mangeris, 94 Nev. at 402, 580 P.2d at 483.

As a threshold matter, to determine whether appellants can maintain a common-law negligence claim against the pharmacies for Copenig's criminal act of driving while under the influence of controlled substances, we must consider the relationship between the parties and if a legal obligation can be imposed upon the pharmacies for the third-party appellants' benefit. The issue of whether, under common-law principles, a special relationship exists between a pharmacy and a third party to justify imposing a duty of care for the third party's benefit is an issue of first impression. We find persuasive to our analysis a Florida District Court of Appeal opinion involving a pharmacy's potential liability to a third party. Dent v. Dennis Pharmacy, Inc., 924 So. 2d 927 (Fla. Dist. Ct. App. 2006).

In Dent, a motorist, Dent, was involved in a collision with a pharmacy patron who drove while under the influence of prescribed medication and fell asleep at the wheel, causing injuries to Dent. 924 So. 2d at 928. Dent filed a negligence action against the pharmacy, alleging that because the pharmacy voluntarily undertook the duty of warning the patron about the prescription drug's effect on driving, the pharmacy owed a duty of care to Dent, the injured motorist. Id. at 929. The pharmacy moved the trial court to dismiss the action on the basis that it owed no

duty to an unidentified third party. The trial court agreed and dismissed Dent's complaint. Id.

On appeal, the Dent court recognized that in the context of professional relationships, the duty element of negligence could be established in one of two ways: (1) a plaintiff having a direct relationship with the defendant, or (2) by establishing that the plaintiff is a known or identifiable third party to whom the defendant owes a legal duty. Id. The court determined that no duty of care was owed to Dent because she had no direct relationship with the pharmacy; the pharmacy merely filled its customer's prescription and warned the customer of the medication's side effects. Id. The court further concluded that Dent was an anonymous member of the driving public and was therefore not a known or identifiable third party. The pharmacy had no control over whether its customer would take the medication and then drive, or even take the medication at all. Id. Therefore, a finding that Dent was a known or identifiable third party to whom the pharmacy owed a legal duty "under those circumstances would create a zone of risk [that] would be impossible to define." Id. (quoting Cheeks v. Dorsey, 846 So. 2d 1169, 1173 (Fla. Dist. Ct. App. 2003)). Thus, the pharmacy's actions did not create a legal duty in favor of the motoring public.

Following the Florida court's reasoning, we conclude that in this matter the pharmacies did not owe a duty to the third-party appellants. The pharmacies have no direct relationship with the third-party appellants. In addition, as in Dent, the appellants in this matter are unidentifiable members of the general public who were unknown to the

pharmacies.<sup>3</sup> Thus, the pharmacies' acts of dispensing prescription drugs to Copening did not create a legal duty. We conclude that the district court did not err in dismissing appellants' negligence causes of action asserted against the pharmacies on this ground.<sup>4</sup>

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<sup>3</sup>We note that, at the time that the underlying accident occurred, the pharmacies had no obligation to do anything after receiving the Task Force letter and only limited authority to refuse to fill any prescriptions. In 2006, however, the Board of Pharmacy amended its regulations, which may have created a special relationship that could justify imposing a duty in favor of third parties. NAC 639.753 provides that if a pharmacist declines to fill a prescription, because in his professional judgment the prescription is (1) fraudulent, (2) potentially harmful to the customer's health, (3) not for a legitimate medical purpose, or (4) filling the prescription would be unlawful, the pharmacist must in a timely manner contact the prescribing physician to resolve the pharmacist's concerns. The amendment further provides that after speaking with the physician, the pharmacist may fill the prescription if "the pharmacist reasonably believes, in his professional judgment, that the prescription is" not fraudulent or harmful to the patient's health or is lawful or for a legitimate medical purpose. NAC 639.753(3)(a)-(d). If one of these conditions is not met, after discussing the prescription with the physician, the pharmacist is mandated not to fill the prescription and must retain the prescription. NAC 639.753(4). We make no determination as to whether this regulation imposes a duty on pharmacies or creates a special relationship with their customers.

<sup>4</sup>Because we conclude that no direct relationship exists between the pharmacies and the third-party appellants, or that appellants are identifiable members of the general public, to impose a duty on pharmacists for the general public's protection, we need not consider whether the pharmacies' actions created foreseeable harm to appellants.

Appellants' additional argument—that a common-law negligence claim is established merely as a result of alleged violations of a professional standard of care—fails. Unlike Mainor v. Nault, 120 Nev. 750, 101 P.3d 308 (2004), where a special relationship existed between the

*continued on next page . . .*



NRS 453.1545's public policy does not create a duty of care for pharmacies

Appellants allege that while NRS 453.1545's language does not expressly require pharmacies to take action to prevent prescription-drug abuse, the statute's language and legislative history implies that pharmacies are required to take action to fulfill the statute's purpose. The pharmacies assert that neither the statute's plain language nor its legislative history demonstrates that the Legislature intended to impose any obligation on pharmacies in favor of third parties. We agree with the pharmacies.

NRS 453.1545(1) requires Nevada's State Board of Pharmacy and the Investigation Division of the Department of Public Safety to create a computerized program to track controlled substance prescriptions that are filled by registered pharmacies or that are dispensed by a registered practitioner. The tracking program is designed to provide information relating to a customer's inappropriate use of specific controlled substances filled by board-registered pharmacies and practitioners:

1. The Board and the Division shall cooperatively develop a computerized program to track each prescription for [specific] controlled substance[s] . . . filled by a pharmacy that is registered with the Board or that is dispensed by a practitioner who is registered with the Board. The program must:

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*. . . continued*

plaintiff, the client, and the plaintiff's attorneys, here, no special relationship exists between appellants and the pharmacies.

(a) Be designed to provide information regarding:

(1) The inappropriate use by a patient of [specific] controlled substances . . . to pharmacies, practitioners and appropriate state agencies to prevent the improper or illegal use of those controlled substances.

NRS 453.1545(1)(a)(1). Although NRS 453.1545(1)(a)(1) states that the information will be provided to pharmacies, subsection 5 of the same statute explains that the "[i]nformation obtained from the program . . . is confidential and, except as otherwise provided by this section . . . must not be disclosed to any person." NRS 453.1545(5).

The Board or Division are required, however, to report any suspected fraud or illegal activity to law enforcement or the appropriate occupational licensing board. NRS 453.1545(4). Thus, while the statute's language states that gathering information related to prescription-drug use and disseminating it to pharmacies and practitioners is to prevent prescription-drug abuse, only the Board or Division may share the information gathered from the pharmacies. Pharmacies and practitioners are expressly prohibited from disclosing any information. NRS 453.1545(5). Further, nothing in NRS 453.1545 requires pharmacies to take action to protect the general public after receiving a Task Force letter. Thus, based on the statute's plain language, it is evident that the Legislature did not intend to create a policy that requires pharmacies to protect third parties from a pharmacy customer's actions.

NRS 453.1545's legislative history further supports our conclusion. The statute's underlying purpose is to computerize a manual system for tracking prescription-drug use, *i.e.*, a recordkeeping system. See Hearings on S.B. 36 Before the Senate Comm. on Human Resources

and Facilities and Before the Assembly Comm. on Health and Human Services, 68th Leg. (Nev., January 25, February 1, June 7, 1995). When suggested to the legislators that another purpose of the computerized program was to identify drug abusers early on before they become "serious drug users, kill themselves or someone else," a legislator responded that the Legislature is not responsible for people's personal decisions and, ultimately, it is the Board's duty to prosecute regulatory violations. Hearing on S.B. 36 Before the Senate Comm. on Human Resources and Facilities, 68th Leg. (Nev., February 1, 1995) (testimony by lobbyist for the Nevada State Board of Pharmacy, and comment by state senator); Hearing on S.B. 36 Before the Assembly Comm. on Ways and Means, 68th Leg. (Nev., June 20, 1995) (comment by committee vice-chair). Subsequently, when it enacted NRS 453.1545, the Legislature declined to impose additional obligations on pharmacies. NRS 453.1545; Hearing on S.B. 36 Before the Senate Comm. on Human Resources and Facilities, 68th Leg. (Nev., February 1, 1995) (testimony by lobbyist for the Nevada State Board of Pharmacy).

Thus, the legislative history demonstrates that NRS 453.1545's enactment was intended to enhance recordkeeping by permitting more thorough and accurate information to be available to enforcement and regulatory authorities and for transmission by the Task Force to physicians, pharmacies, and others. We therefore reject appellants' contention that NRS 453.1545 creates a public policy duty for pharmacies to protect third parties.

Nevada's pharmacy statutes and regulations do not support appellants' negligence per se claim against the pharmacies

Appellants assert that the district court erred in dismissing their negligence per se claim against the pharmacies because the

pharmacies violated a number of Nevada statutes and regulations enacted to protect the general public, of whom the appellants are members, from the unlawful distribution of controlled substances.<sup>5</sup> The pharmacies counter that the statutes and regulations relied on by appellants do not mandate that a pharmacist must refuse to fill a valid prescription for the general public's protection.

A negligence per se claim arises when a duty is created by statute. Torrealba v. Kesmetis, 124 Nev. 95, 178 P.3d 716 (2008). A civil statute's violation establishes the duty and breach elements of negligence when the injured party is in the class of persons whom the statute is intended to protect and the injury is of the type against which the statute is intended to protect. Ashwood v. Clark County, 113 Nev. 80, 86, 930 P.2d 740, 744 (1997); Sagebrush Ltd. v. Carson City, 99 Nev. 204, 208, 660 P.2d 1013, 1015 (1983). But a statute that regulates the communication of

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<sup>5</sup>Appellants cite to the following statutes and regulations to support their negligence per se claim: NRS 453.1545 (creating computerized program to track prescriptions for controlled substances); NRS 453.256 (outlining requirements for dispensing specific controlled substances); NRS 453.257 (prohibiting the filling of second or subsequent prescriptions for certain controlled substances "unless the frequency of prescriptions is in conformity with the directions for use" and the increased amount is verified by the practitioner personally by telephone or in writing); NRS 639.2392 (establishing requirements for maintaining patient records); NRS 639.2393 (establishing limitations on filling controlled substance prescriptions); NAC 639.485 (concerning the maintenance of records for controlled substances); NAC 639.742 (discussing the duties and authority of a dispensing practitioner to dispense controlled substances); NAC 639.745 (outlining duties concerning dispensing controlled substances); NAC 639.926 (regarding dispensing controlled substances to certain individuals and maintaining records).

information regarding the administration of drugs does not impose a duty on a pharmacy that runs to an unidentifiable third party. Crippens v. Sav On Drug Stores, 114 Nev. 760, 763 n.1, 961 P.2d 761, 763 n.1 (1998).

The statutes and regulatory provisions the appellants rely on to assert a negligence per se claim against the pharmacies are not intended for the general public's protection or to protect against any injury that the third-party appellants may have sustained. The duty owed under these statutes or regulations is to the person for whom the prescription was written, the pharmacy's customer, if anyone, and not for the general public's protection. And although various statutory and regulatory provisions may express standards of care for the practice of pharmacology, under the circumstances of this case, those standards of care do not extend to unidentified third parties. Therefore, we conclude that the district court properly dismissed appellants' negligence per se claims asserted against the pharmacies.<sup>6</sup>

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<sup>6</sup>The pharmacies contend that Nevada State Board of Pharmacy v. Garrigus, 88 Nev. 277, 496 P.2d 748 (1972), is dispositive of appellants' negligence per se claim. But Garrigus is inapposite to our consideration of whether the pharmacies owed a duty to appellants, as that case concerned whether the Nevada State Board of Pharmacy's decision to revoke several pharmacists' licenses was supported by substantial evidence. Id. at 278-79, 496 P.2d at 749.

## CONCLUSION

We affirm the district court's order dismissing appellants' action against the pharmacies for failure to state a claim upon which relief can be granted.<sup>7</sup>

/s/ Hardesty, C.J.  
Hardesty

We concur:

Parraguirre, J.  
Parraguirre

Gibbons, J.  
Gibbons

Douglas, J.  
Douglas

Pickering, J.  
Pickering

<sup>7</sup>After briefing in this appeal had concluded, appellants filed a supplemental brief. In that supplemental brief, appellants provided additional authority, which was available when their reply brief was filed, and appellants asserted a new argument that was not previously raised in their opening or reply briefs. We did not consider the arguments raised in appellants' supplemental brief because they exceeded the scope of NRAP 31. See U.S. v. Vazquez-Rivera, 407 F.3d 476, 487 (1st Cir. 2005) (considering authority raised in a supplemental brief that were not raised in the opening brief because there was an intervening change in law); U.S. v. Khoroizian, 333 F.3d 498, 506 n.7 (3d Cir. 2003) (providing that FRAP 28(j) cannot be used to raise supplemental arguments); U.S. v. Kimler, 335 F.3d 1132, 1138 n.6 (10th Cir. 2003) (refusing to consider an argument that should have been raised in the party's opening or reply brief).

CHERRY, J., with whom SAITTA, J., agrees, dissenting:

I differ with my colleagues as to their resolution of this appeal. In particular, I conclude that the district court erred when it granted the pharmacies' motions to dismiss because the appellants have sufficiently stated common-law negligence and negligence per se claims that preclude dismissal. I therefore dissent.

### DISCUSSION

#### Common-law negligence cause of action

The majority concludes that no special relationship exists to extend a duty of care from the pharmacies to the third-party appellants. I disagree with this conclusion. This court has recognized a special relationship between an innkeeper-guest, teacher-student, and employer-employee. See Lee v. GNLV Corp., 117 Nev. 291, 295, 22 P.3d 209, 212 (2001). The relationship between a pharmacy and pharmacy customer should also be considered a special relationship. Thus, in my opinion, appellants' allegations in their complaint are legally sufficient to constitute a common-law negligence cause of action.

Generally, a defendant does not have a duty to control another's dangerous conduct or to warn others when dangerous conduct arises. Mangeris v. Gordon, 94 Nev. 400, 402, 580 P.2d 481, 483 (1978). But an exception to this general rule occurs when a special relationship exists between the defendant and the actor who allegedly caused the injury. Id. If a special relationship exists, the defendant has a duty to take measures to protect foreseeable victims from foreseeable harm. See Elko Enterprises v. Broyles, 105 Nev. 562, 565-66, 779 P.2d 961, 964 (1989); El Dorado Hotel v. Brown, 100 Nev. 622, 627, 691 P.2d 436, 440 (1984), overruled on other grounds by Vinci v. Las Vegas Sands, 115 Nev. 243, 984 P.2d 750 (1999). Here, contrary to the majority's position, I

determine that the pharmacies owed appellants a duty of care to, among other things, investigate the validity of Copening's prescriptions or to refuse to fill her prescriptions, if warranted, based on the special relationship that exists between a pharmacist and pharmacy customer, together with the information distributed by the Task Force. While I conclude that sufficient information exists to reverse the district court's dismissal of appellants' common-law negligence claim, because the underlying proceedings are at an early stage of the litigation, there also remain unanswered questions relating to foreseeability that justify remanding this appeal to the district court for further proceedings.

Special relationship element of common-law negligence cause of action

A pharmacist's professional standards of care, considered with the notice contained in the Task Force letter, justifies extending the duty owed by the pharmacies under a common-law negligence cause of action to these appellants. Not only do pharmacists possess an expertise in the dispensation of prescription drugs, NRS 639.213; NRS 639.0124(4), as recognized by the majority, but pharmacists must ensure that the drugs sought by a customer are "dispensed only for medically necessary purposes and according to prevailing standards of care for practitioners practicing in the specialty claimed or practiced by the dispensing practitioner." NAC 639.742(3)(h). Nevada's Legislature has recognized that pharmacists are trained to recognize potential drug abuse based on the frequency of a drug's refill and dosages. NRS 639.0124; NAC 639.707(4). Before filling a prescription, a pharmacist must review a customer's records to determine the prescription's therapeutic appropriateness by considering possible drug abuse, overuse of a particular drug, adverse side effects, or improper dosages or treatment durations. NAC 639.707(4). If a pharmacist



reasonably believes that a prescription for a controlled substance was not issued in the normal course of a professional's practice, a pharmacist is prohibited from filling the prescription. NRS 453.381(4).

Based on a pharmacist's professional standards of care, the Legislature contemplated that pharmacists may be subject to civil liability for improperly dispensing prescription drugs when it enacted NRS 453.256(6). This statute provides that civil liability cannot be imposed upon a pharmacist if the pharmacist acts in "good faith in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment," implying that civil liability could arise if the good faith requirement is not met. See also International Game Tech. v. Dist. Ct., 122 Nev. 132, 154, 127 P.3d 1088, 1103 (2006) (noting that this court presumes that when the Legislature enacts a statute it does so "with full knowledge of existing statutes relating to the same subject" (internal quotes and citation omitted)). Consequently, the special relationship between a pharmacist and pharmacy customer, entails more than blindly filling prescriptions, and thus, a special relationship is created between a pharmacist and customer when a prescription is filled.

Generally, the relationship between a customer and pharmacist does not establish a duty in favor of third parties. This case, however, includes a component that the majority ignores—notice. The actual notice to the pharmacies contained in the Task Force letter (which, according to the complaint, was sent to and received by all the pharmacies in this action), together with a pharmacist's professional standard of care, noted above, clearly refutes the majority's conclusion that no special

relationship exists to justify extending a duty of care owed by the pharmacies to the appellants.

Appellants' second amended complaint alleges that the pharmacies that received the Task Force letter outlining Copening's prescription-filling activities were informed that Copening had received 4,500 hydrocodone pills within a 12-month period by having numerous prescriptions filled at 13 different pharmacies.<sup>1</sup> The complaint also contends that despite receiving the Task Force letter the pharmacies continued to fill narcotic or SOMA prescriptions for Copening.<sup>2</sup> It is unclear why Copening was filling prescriptions for this amount of narcotic medication within a year's time. But the pharmacies had, at a minimum, inquiry notice that continuing to fill Copening's prescriptions for hydrocodone or SOMA could result in harm to herself or others. See Ogle v. Salamatof Native Ass'n, Inc., 906 F. Supp. 1321, 1326 (D. Alaska 1995) (explaining that inquiry notice exists when one has knowledge of facts that would lead a reasonable and prudent person using ordinary care to make further inquiries).

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<sup>1</sup>Hydrocodone is a narcotic pain reliever used for the relief of moderate to moderately severe pain and has a high potential for abuse. Physicians' Desk Reference 3143-44 (63d ed. 2009); NRS 453.176; NAC 453.520. It may impair one's mental or physical abilities required for the performance of potentially hazardous tasks, such as driving a car. Physicians' Desk Reference 3143-44 (63d ed. 2009).

<sup>2</sup>SOMA, also known as carisoprodol, is used for the relief of acute pain. Physicians' Desk Reference 1931 (63d ed. 2009). It is recommended that it only be used for "acute treatment periods up to two or three weeks," and it also may impair one's ability to operate a motor vehicle. Id. According to appellants' complaint, the combination of hydrocodone and SOMA is known as "The Vegas Cocktail."

Here, the pharmacists had a duty to review Copening's prescription records, including giving consideration to the Task Force letter, before filling her next prescription. In light of the Task Force letter identifying Copening's prescription history, the pharmacies were required to evaluate the prescription's therapeutic appropriateness (considering possible drug abuse, overuse of a particular drug, or improper dosages or treatment durations). NAC 639.707(4). In their professional analysis, if the pharmacists reasonably believed that Copening's prescriptions for hydrocodone were not issued in the normal course of her physician's practice, they were prohibited from filling the prescriptions. NAC 639.742(3)(h); NRS 453.381(4). Thus, the pharmacists owed appellants a duty to exercise that standard of care that is required of the pharmacy profession in the same or similar circumstances. See Dooley v. Everett, 805 S.W.2d 380 (Tenn. Ct. App. 1990); see also Pittman v. Upjohn Co., 890 S.W.2d 425, 434 (Tenn. 1994) (suggesting that because a pharmacy has a duty to do more than fill a customer's prescription correctly, a pharmacy may owe a duty to a noncustomer).

For these reasons, I conclude that the first element to the common-law exception for a duty of care has been established. The next issue presented is whether the harm created by the pharmacies' dispensation of the drugs to Copening was foreseeable.

Foreseeability element of common-law negligence cause of action

This court has held that "[a] negligent defendant is responsible for all foreseeable consequences proximately caused by his or her negligent act." Taylor v. Silva, 96 Nev. 738, 741, 615 P.2d 970, 971 (1980). A defendant's liability can be extinguished when an unforeseeable intervening cause occurs between a defendant's negligence and a plaintiff's injury. El Dorado Hotel v. Brown, 100 Nev. 622, 628-29, 691

P.2d 436, 441 (1984), overruled on other grounds by Vinci v. Las Vegas Sands, 115 Nev. 243, 984 P.2d 750 (1999). But when a "third party's intervening intentional act is reasonably foreseeable, a negligent defendant is not relieved of liability." Id. at 629, 691 P.2d at 441. The issue of foreseeability, thus, can be a mixed question of law and fact. Elko Enterprises v. Broyles, 105 Nev. 562, 566, 779 P.2d 961, 964 (1989). Because the majority concludes that no special relationship exists between the pharmacies and third-party appellants to establish a duty of care owed to appellants, they decline to reach the foreseeability issue. As noted above, however, I conclude that the relationship between the pharmacy and its customer is sufficient to establish the first duty element and that sufficient allegations were pleaded by appellants to address the foreseeability element that precluded the district court from dismissing the common-law negligence cause of action.

According to appellants' second amended complaint, the Task Force notified the pharmacies that Copening was potentially abusing drugs. The Task Force informed each pharmacy that Copening went, during a 12-month period, to multiple pharmacies to fill her prescriptions. According to appellants, in the months before the accident, the pharmacies continued to fill Copening's prescriptions for hydrocodone and SOMA and that the amount of prescriptions filled for Copening provided her with at least 25 pills a day. Why Copening obtained this amount of a narcotic prescription in a 12-month period is not clear, but it may involve misuse of prescription drugs. In my view, these are reasonable inferences that could be drawn from the facts alleged in the appellants' complaint, and the district court was required to accept them as true. See Malfabon v. Garcia, 111 Nev. 793, 796, 898 P.2d 107, 108 (1995) (providing that, in the

context of a motion to dismiss under NRCP 12(b)(5), the plaintiff's allegations are taken as true and every reasonable inference is resolved in plaintiff's favor). Thus, it may have been reasonably foreseeable that Copenig could not be expected to take the medication as prescribed and would drive while under the prescription drug's influence. A natural consequence of those combined actions was that Copenig could cause harm to herself or others.

Although the appellants' allegations are not conclusive of the pharmacies' potential liability, appellants were not required to prove their claim against the pharmacies while defending a motion to dismiss. See Malfabon, 111 Nev. at 796, 898 P.2d at 108. At a minimum, questions of fact remain as to whether the pharmacies had actual or inquiry notice that Copenig was potentially abusing drugs and that she was purportedly pharmacy shopping. Thus, I conclude that sufficient allegations, raised in appellants' pleadings, regarding foreseeability exist and coupled with my determination that a special relationship, together with the actual notice received by the pharmacies, exists to support imposing a duty on the pharmacies for appellants' benefit. I would reverse and remand this issue to the district court for further proceedings.

Negligence per se cause of action that precludes dismissal

The majority concludes that a negligence per se claim is unavailable to appellants because the statutes and regulations relied on by appellants were not intended for the general public's protection or to protect against any injury that third parties may sustain. I disagree.

A negligence per se claim is available when a defendant violates a statute that is designed to protect others against the type of injury that was incurred. Ashwood v. Clark County, 113 Nev. 80, 86, 930 P.2d 740, 744 (1997). The Legislature has recognized that pharmacology

affects public safety and welfare. NRS 639.213. Consequently, the Legislature regulates the profession, including in what manner and when controlled substances may be dispensed. See NRS 639.2171; NRS 639.0124; NRS 453.381. To that end, the Legislature directed the Board of Pharmacy to adopt regulations "as are necessary for the protection of the public, appertaining to the practice of pharmacy." NRS 639.070(1)(a).

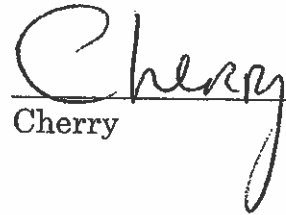
Nevada law requires pharmacists to review customers' records before filling prescriptions to determine prescriptions' therapeutic appropriateness. NAC 639.707(4). Pharmacists must ensure that the substance is being dispensed solely for medically necessary purposes and in accordance with prevailing professional standards of care. NAC 639.742(3)(h).

Based on the enactment of these statutory and regulatory provisions, it is apparent to me that the Legislature intended to prevent pharmacy shopping and the overfilling of certain controlled substances, and ultimately, to protect the general public from prescription-drug abuse and its effects. The abuse of either hydrocodone or SOMA can impair one's driving ability. In my opinion, motorists, like appellants, who are injured by an individual who is driving under the influence of prescription drugs are in the class of persons that the Legislature intended to protect and the injury is a type that the statutes and regulations intended to prevent. Having reached this conclusion, I would reverse the district court's dismissal of appellants' negligence per se claim and remand this matter to the district court for additional proceedings.


#### CONCLUSION

In my view, the appellants' complaint sufficiently states a common-law negligence cause of action because the special relationship and foreseeability elements to create an affirmative duty on the

pharmacies to act for the appellants' benefit have been adequately pleaded. The appellants' negligence per se claim should similarly not have been dismissed under NRCP 12(b)(5), as the elements of that claim have also been met. In light of the above, I would reverse the district court's order and remand this matter to the district court to allow appellants' claims to proceed against those pharmacies that had actual or inquiry notice of the driver's prescription-filling activities. For these reasons, I dissent.

\_\_\_\_\_, J.  
Cherry

I concur:

\_\_\_\_\_, J.  
Saitta

Blank



## **EXECUTIVE SECRETARY REPORT – JANUARY 2010**

### **A) FINANCIAL REPORT**

### **B) INVESTMENT REPORT**

### **C) TEMPORARY LICENSES**

### **D) STAFF ACTIVITIES**

1. Meetings
  - a. CE: 12/11/09 – “Inspecting for Safety”

### **E) REPORT TO BOARD**

1. AB128 Marketing Code of Conduct Compliance Report
2. Health Department Fax Blasts

### **F) BOARD RELATED NEWS**

1. ICPT Update

### **G) ACTIVITIES REPORT**

Blank

**TEMPORARY LICENSES**  
(Issued since last board meeting)

No temporary licenses have been issued since last board meeting.

Blank

**NEVADA STATE BOARD OF  
PHARMACY**

**AB128 MARKETING CODE  
OF CONDUCT ANNUAL  
COMPLIANCE REPORT  
2009**

NEVADA STATE BOARD OF PHARMACY  
431 WEST PLUMB LANE  
RENO, NEVADA 89509  
(775) 850-1440  
FAX: (775) 850-1444  
WEBSITE: [BOP.NV.GOV](http://BOP.NV.GOV)  
E-MAIL: [PHARMACY@GOVMAIL.STATE.NV.US](mailto:PHARMACY@GOVMAIL.STATE.NV.US)

## INTRODUCTION

In the interest of better serving the people of Nevada, AB128 was introduced in the Nevada assembly on February 20<sup>th</sup>, 2007. The intent of AB128 was to have manufacturers and wholesalers adopt a marketing code of conduct based on applicable legal standards and incorporate principles of health care, including, without limitation, requirements that the activities of the wholesaler or manufacturer be intended to benefit patients, enhance the practice of medicine and not interfere with the independent judgment of health care professionals.

AB128 also amends NRS 639.238 to clarify provisions concerning the confidentiality of the contents of a prescription.

Existing law prohibits a person from manufacturing or engaging in the wholesale distribution of certain drugs unless the person is licensed to do so by the State Board of Pharmacy. (NRS 639.100, 639.233)

Existing law provides that prescriptions filed at a pharmacy are not a public record and prohibits, with certain exceptions, a pharmacist from divulging the contents of a prescription. (NRS 639.238) Section 2 of this bill clarifies that this prohibition applies to the divulgence of the name of the prescribing medical practitioner.

NRS 639.570 as adopted requires the adoption of a marketing code of conduct, requires reporting of training and investigative policies and requires submission of certain information to the Board for any wholesaler or manufacturer who sells or markets a drug, medicine, chemical device or appliance in Nevada.

### Business Practices

**NRS 639.570 Employees of wholesalers or manufacturers; adoption of marketing code of conduct; training; investigation policies; submission of information to Board; Board to report certain information to Governor and Legislature; duties of Board.**

1. A wholesaler or manufacturer who employs a person to sell or market a drug, medicine, chemical, device or appliance in this State shall:

(a) Adopt a written marketing code of conduct which establishes the practices and standards that govern the marketing and sale of its products. The marketing code of conduct must be based on applicable legal standards and incorporate principles of health care, including, without limitation, requirements that the activities of the wholesaler or manufacturer be intended to benefit patients, enhance the practice of medicine and not interfere with the independent judgment of health care professionals. Adoption of the most recent version of the Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America satisfies the requirements of this paragraph.

(b) Adopt a training program to provide regular training to appropriate employees, including, without limitation, all sales and marketing staff, on the marketing code of conduct.

(c) Conduct annual audits to monitor compliance with the marketing code of conduct.

(d) Adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct, including, without limitation, the maintenance of effective lines of communication for employees to report noncompliance, the investigation of reports of noncompliance, the taking of corrective action in response to noncompliance and the reporting of instances of noncompliance to law enforcement authorities in appropriate circumstances.

(e) Identify a compliance officer responsible for developing, operating and monitoring the marketing code of conduct.

2. A wholesaler or manufacturer who employs a person to sell or market a drug, medicine, chemical, device or appliance in this State shall submit to the Board annually:

- (a) A copy of its marketing code of conduct;
  - (b) A description of its training program;
  - (c) A description of its investigation policies;
  - (d) The name, title, address, telephone number and electronic mail address of its compliance officer;
- and
- (e) Certification that it has conducted its annual audit and is in compliance with its marketing code of conduct.
3. On or before January 15 of each odd-numbered year, the Board shall prepare and submit to the Governor, and to the Director of the Legislative Counsel Bureau for transmittal to the Legislature, a compilation of the information submitted to the Board pursuant to this section, other than any information identified as a trade secret in the information submitted to the Board.
4. The Board:
- (a) Shall adopt regulations providing for the time of the submission and the form of the information required pursuant to this section and defining "compliance" for the purposes of this section.
  - (b) May not require the disclosure of the results of an audit conducted pursuant to this section.
  - (c) Shall post on its Internet website information concerning the compliance of all wholesalers and manufacturers with the requirements of this section.
  - (d) Shall not disclose any proprietary or confidential business information that it receives pursuant to this section.
- (Added to NRS by 2007, 1791)

## **The Board**

**LCB File No. R122-07 (Effective January 30, 2008)**

**NRS 639.570 4. (a) Requires that the Board of Pharmacy adopt regulations for the time, form of information submission and define compliance.**

The Board adopted LCB File No. R122-07 (Effective January 30, 2008)

In LCB file No. R122-07 the Board adopted two Codes of Conduct by reference:

1. The Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America and
2. The Code of Ethics on Interactions with Health Care Professionals adopted by the Advanced Medical Technology Association.

Manufacturers or Wholesalers that adopt one of these two Codes of Conduct and meet other criteria adopted in LCB file R122-07 are deemed compliant.

Manufacturers or Wholesalers that have not adopted one of the two Codes of Conduct are required to provide their Code of Conduct for review. The Manufacturer or Wholesaler's Code of Conduct must address all the subjects in one of the two reference codes of conduct to be considered compliant.

Other information all wholesalers and manufacturers must provide to be deemed compliant include:

1. A description of their training program and how the company provides regular training programs to appropriate employees, including, without limitation, all sales and marketing staff, on the marketing code of conduct.
2. A description of their policies and procedures for investigating instances of noncompliance with the marketing code of conduct, including, without limitation, the maintenance of effective lines of

communication for employees to report noncompliance, the investigation of reports of noncompliance, the taking of corrective action in response to noncompliance and the reporting of instances of noncompliance to law enforcement authorities in appropriate circumstances.

3. The company must identify a compliance officer responsible for developing, operating and monitoring the marketing code of conduct.
4. The company must conduct annual audits to monitor compliance with the marketing code of conduct they have adopted.

After the initial submission year each manufacturer or wholesaler must submit to the Board annually:

- (a) A copy of its marketing code of conduct;
  - (b) A description of its training program;
  - (c) A description of its investigation policies;
  - (d) The name, title, address, telephone number and electronic mail address of its compliance officer;
- and
- (e) Certification that it has conducted its annual audit and is in compliance with its marketing code of conduct

### **Overview of Compliance Results 2009**

1. 501 companies, affiliated companies, or subsidiaries are posted on the Board website as compliant.
2. 3 companies have been contacted to provide additional information to evaluate their compliant status
3. 2 companies have been determined to be exempt from AB128 since the wholesaler or manufacturer does not employ a person to sell or market a drug, medicine, chemical, device or appliance in Nevada.
4. In 2008, 337 companies, affiliated companies, or subsidiaries were listed as compliant and 12 companies requested and were granted exempt status.

### **Status of the Board Website**

1. The Board website of companies, affiliated companies, or subsidiaries compliant is updated monthly or as needed.





## In This Issue:

- ♦ Updated CDC Recommendations for Testing, Treatment and Chemoprophylaxis of Influenza for the 2009-10 Influenza Season

September 16, 2009

Vol. 29, No.12

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## UPDATED CDC RECOMMENDATIONS FOR TESTING, TREATMENT AND CHEMOPROPHYLAXIS OF INFLUENZA FOR THE 2009-10 INFLUENZA SEASON

*The following provides a brief summary of information released September 8, 2009 from CDC.*

*The complete document can be accessed at: <http://www.cdc.gov/h1n1flu/recommendations.html>.*

### TESTING USING rRT-PCR

At this time, testing for 2009 H1N1 (novel H1N1) influenza infection with real-time reverse transcriptase-polymerase chain reaction (rRT-PCR) **should be limited to persons with suspected or confirmed influenza REQUIRING HOSPITALIZATION.**

### RECOMMENDED ANTIVIRALS

At this time, recommended antivirals for treatment or chemoprophylaxis of influenza during the 2009-10 influenza season include oseltamivir (trade name Tamiflu®) or zanamivir (trade name Relenza®). Recommendations for their use are included below. See Tables 1 and 2 (following page) for dosage recommendations. These recommendations may change if there is a change in the predominant circulating influenza strain(s) and will be updated in future editions of the Epi-News.

### ANTIVIRAL TREATMENT

#### Recommendations:

- 1) Treatment is recommended for all hospitalized patients with confirmed, probable or suspected 2009 H1N1 or seasonal influenza.
- 2) Treatment generally is recommended for patients who are at higher risk for influenza-related complications:
  - Children younger than 5 years old. However, the risk for severe complications from seasonal influenza is highest among children younger than 2 years old.
  - Adults 65 years of age or older.
  - Pregnant women.
  - Persons with the following conditions:
    - Chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus);
    - Immunosuppression, including that caused by medications or by HIV;
    - Persons younger than 19 years of age who are receiving long-term aspirin therapy, because of an increased risk for Reye syndrome.
- 3) Treatment should be initiated empirically when the decision is made to treat patients who have illnesses that are clinically compatible with influenza. Treatment should not await laboratory confirmation because laboratory testing can sometimes delay treatment and because a negative rapid test does not rule out influenza. (For more information on the use of rapid influenza diagnostic tests go to: [http://www.cdc.gov/h1n1flu/guidance/rapid\\_testing.htm](http://www.cdc.gov/h1n1flu/guidance/rapid_testing.htm)).

#### Notes on antiviral treatment:

- ♦ Persons who are not at higher risk for complications or do not have severe influenza requiring hospitalization generally do not require antiviral medications for treatment or prophylaxis. However, any suspected influenza patient presenting with warning symptoms (e.g., dyspnea) or signs (e.g., tachypnea,

unexplained oxygen desaturation) of lower respiratory tract illness should promptly receive empiric antiviral therapy.

- ♦ Clinical judgment is an important factor in antiviral treatment decisions for all patients presenting for medical care who have illnesses consistent with influenza.
- ♦ Treatment should be initiated as early as possible because studies show that treatment initiated early (i.e. within 48 hours of illness onset) is more likely to provide benefit.
- ♦ Patients with obesity (body mass index 30 to 39) or morbid obesity (body mass index  $\geq 40$ ) should be carefully evaluated for the presence of underlying medical conditions that are known to increase the risk for influenza complications, and receive empiric treatment when these conditions are present, or if signs of lower respiratory tract infection are present.

### ANTIVIRAL CHEMOPROPHYLAXIS

**Post-exposure antiviral chemoprophylaxis can be considered for the following:**

- ♦ Persons who are at higher risk for complications of influenza and are a **close contact\*** of a person with confirmed, probable, or suspected 2009 H1N1 or seasonal influenza during that person's infectious period.
- ♦ Health care personnel, public health workers, or first responders who have had a recognized, unprotected **close contact\*** exposure to a person with confirmed, probable, or suspected 2009 H1N1 or seasonal influenza during that person's infectious period. Information on appropriate personal protective equipment is available on CDC's website at: [http://www.cdc.gov/h1n1flu/guidelines\\_infection\\_control.htm](http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm).

**\*Close contact** is defined as having cared for or lived with a person who is a confirmed, probable or suspected case of influenza, or having been in a setting where there was a high likelihood of contact with respiratory droplets and/or body fluids of such a person. Examples of close contact include sharing eating or drinking utensils, physical examination, or any other contact between persons likely to result in exposure to respiratory droplets. Close contact typically does not include activities such as walking by an infected person or sitting across from a symptomatic patient in a waiting room or office.

#### Notes on antiviral chemoprophylaxis:

- ♦ Chemoprophylaxis generally is not recommended if more than 48 hours have elapsed since the last contact with an infectious person.
- ♦ Chemoprophylaxis is not indicated when contact occurred before or after, but not during, the ill person's infectious period. Although infected persons may shed influenza virus beginning one day before they develop symptoms to up to 7 days after they become ill, **for this guidance, the infectious period for influenza is defined as one day before until 24 hours after fever ends.**
- ♦ Antiviral agents should not be used for post-exposure chemoprophylaxis in healthy children or adults based on potential exposures in the community, school, camp or other setting.

Please share this document with all physicians & staff in your facility/office.

**Table 1. Antiviral medication dosing recommendations  
for treatment or chemoprophylaxis of 2009 h1n1 infection**  
(reprinted from: <http://www.cdc.gov/h1n1flu/recommendations.htm#table1>)

Agent, group		Treatment (5 days)	Chemoprophylaxis (10 days)
<b>Oseltamivir (Tamiflu®)</b>			
<b>Adults</b>		75-mg capsule twice per day	75-mg capsule once per day
<b>Children ≥ 12 months</b>	<b>15 kg or less</b>	60 mg per day divided into 2 doses	30 mg once per day
	<b>16-23 kg</b>	90 mg per day divided into 2 doses	45 mg once per day
	<b>24-40 kg</b>	120 mg per day divided into 2 doses	60 mg once per day
	<b>&gt;40 kg</b>	150 mg per day divided into 2 doses	75 mg once per day
<b>Zanamivir (Relenza®)</b>			
<b>Adults</b>		Two 5-mg inhalations (10 mg total) twice per day	Two 5-mg inhalations (10 mg total) once per day
<b>Children</b>		Two 5-mg inhalations (10 mg total) twice per day (age, 7 years or older)	Two 5-mg inhalations (10 mg total) once per day (age, 5 years or older)

**Notes:**

- ♦ Pregnant women are known to be at higher risk for complications from infection with seasonal influenza viruses, and severe disease among pregnant women was reported during past pandemics.
- ♦ Hospitalizations and deaths have been reported among pregnant women with 2009 H1N1 influenza virus infection, and one study estimated that the risk for hospitalization for 2009 H1N1 influenza was four times higher for pregnant women than for the general population.
- ♦ While oseltamivir and zanamivir are "Pregnancy Category C" medications, indicating that no clinical studies have been conducted to assess the safety of these medications for pregnant women, the available risk-benefit data indicate pregnant women with suspected or confirmed influenza should receive prompt antiviral therapy.
- ♦ Pregnancy should not be considered a contraindication to oseltamivir or zanamivir use. Because of its systemic activity, oseltamivir is preferred for treatment of pregnant women.
- ♦ The drug of choice for chemoprophylaxis is less clear. Zanamivir may be preferable because of its limited systemic absorption; however, respiratory complications that may be associated with zanamivir because of its inhaled route of administration need to be considered, especially in women at risk for respiratory problems.

**Table 2. Dosing recommendations for antiviral treatment or chemoprophylaxis  
of children younger than 1 year using oseltamivir\***

(reprinted from: <http://www.cdc.gov/h1n1flu/recommendations.htm#table2>)

Age	Recommended treatment dose for 5 days	Recommended prophylaxis dose for 10 days
Younger than 3 months	12 mg twice daily	Not recommended unless situation judged critical due to limited data on use in this age group
3-5 months	20 mg twice daily	20 mg once daily
6-11 months	25 mg twice daily	25 mg once daily

\*Oseltamivir is authorized for emergency use in children < 1 year of age under an Emergency Use Authorization (EUA) issued by FDA, subject to the terms and conditions of the EUA. Additional information is at: <http://www.cdc.gov/h1n1flu/eua/tamiflu.htm>.

**Notes:**

- ♦ Some experts prefer weight-based dosing for children aged younger than 1 year, particularly for very young or premature infants based on preliminary data from a National Institutes of Health funded Collaborative Antiviral Study Group (CASG). When using weight-based dosing for infants aged younger than 1 year for treatment, those 9 months or older should receive 3.5 mg/kg/dose BID, and those aged younger than 9 months should receive 3.0 mg/kg/dose BID. When using weight-based dosing for infants aged younger than 1 year for chemoprophylaxis, those 9 months or older should receive 3.5 mg/kg/dose QD, and those aged younger than 9 months should receive 3.0 mg/kg/dose QD (Source: D Kimberlin et al. Oseltamivir (OST) and OST Carboxylate (CBX) Pharmacokinetics (PK) in Infants: Interim Results from a Multicenter Trial. Abstract accepted to Infectious Diseases Society of America meeting, October 2009).
- ♦ Health care providers should be aware of the lack of data on safety and dosing when considering oseltamivir use in a seriously ill young infant with confirmed 2009 H1N1 influenza virus infection or who has been exposed to a confirmed 2009 H1N1 influenza case, and carefully monitor infants for adverse events when oseltamivir is used. Additional information on oseltamivir for this age group can be found at: <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM153547.pdf>.



# EPI - NEWS

Page 1 of 1

## PHYSICIAN ALERT:

- ♦ Clinicians Advised to Discontinue Use of Propofol from Tainted Lots –United States, 2009

July 13, 2009

Vol. 29, No. 6

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This alert contains information on investigations in progress and/or diagnoses that may not yet be confirmed.

The Physician Alert is intended primarily for the use of local health care providers, should be considered privileged, and should NOT be distributed further.

## Clinicians Advised to Halt Use of Propofol from Tainted Lots<sup>1</sup>

The Centers for Disease Control and Prevention (CDC) has been investigating recent cases of febrile reactions among patients undergoing endoscopy in the United States.

This investigation has revealed that all of the case-patients received the anesthetic propofol from 100 mL vials manufactured by Teva Pharmaceutical Industries. Testing done by the Food and Drug Administration (FDA) has found that two lots of this product that were in use in facilities reporting reactions were positive for elevated levels of endotoxin.

The lots are **31305429B** and **31305430B**. **Teva Pharmaceuticals is initiating a voluntary recall for these lots, and clinicians are advised to immediately stop using these lots of Teva Pharmaceuticals propofol.** CDC, FDA and Teva Pharmaceutical Industries are continuing to investigate this issue.

If you have any questions, please visit the website [www.tevapharm.com](http://www.tevapharm.com) or contact Teva Pharmaceuticals USA at 1-215-591-3000.

### ATTENTION!

This is an important warning message. Please share this document with all physicians & staff in your facility/office.

<sup>1</sup> CDC. The Epidemic Information Exchange. Clinicians Advised to Discontinue Use of Propofol from Tainted Lots – United States, 2009. July 13, 2009.

Blank

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November 30, 2009

Carmen Catizone, MS, RPh, DPh  
Executive Director/Secretary  
National Association of Boards of Pharmacy  
1600 Feehanville Drive  
Mount Prospect, IL 60056-6014

Dr. Catizone,

Thank you for your October 30, 2009 letter of inquiry regarding the merger of ICPT and ATI. I do hope you received the announcement letter from October. The letter was written to inform our stakeholders of the exciting news but to also convey that there were **no changes** to management of the program, the administration of the exam or the policies governing the certification of pharmacy technicians granted by the ExCPT. The ICPT office remains in St. Charles Missouri with the existing staff in place to administer the credentialing program, and, I remain instrumental in the ongoing direction of pharmacy technician training and certification as part of the ATI team. This merger brings me a wealth of resources in sales, marketing and psychometric support that will only enhance the existing product.

The governance of the credentialing program remains in place and unchanged. To be clear, there are no changes in eligibility for the exam or any other policies. Policy change is only made by the Certification Governing Committee. This has been communicated to NOCA/ICE and acknowledged by them. The ExCPT continues to be a pharmacy program governed by pharmacists and pharmacy technicians; similar to the program you have a governing and financial interest in. Any implication otherwise is incorrect.

I apologize for any misunderstanding on our attempted communications. I last had asked in an email of 8/20/09 for some dates in September. I hope that email did not land in your junk/spam folder. I am glad we have a date for further discussion. I have asked Steve Fredette, CEO of ATI, to respond specifically to additional questions posed in your letter. We look forward to our meeting in December.

Sincerely,

A handwritten signature in cursive script that reads "Rebecca M. Rabbitt". The signature is written in dark ink and is positioned above the printed name and title.

Rebecca M. Rabbitt, MS, PharmD  
Executive Director, Pharmacy Solutions  
Sponsors of ExCPT

Cc: Steve Fredette, CEO  
Executive Directors, Boards of Pharmacy





**nabp**

**National Association of Boards of Pharmacy**

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
 FROM: Carmen Catizone, Executive Director/Secretary  
 DATE: December 23, 2009  
 RE: Update on Technician Certification

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In a recent update to the state boards of pharmacy we noted that a meeting with representatives of Assessment Technologies Institute, L.L.C. (ATI), would be occurring on December 16th. I am pleased to report that the meeting did take place and we had the opportunity to meet with the chief executive officer of ATI, Steve Fredette, and Rebecca Rabbit, executive director of Pharmacy Solutions. I am also pleased to report that the meeting was productive and it appears that we have gained a better understanding of the situation and established a desire to move forward to address questions which have been raised by the state boards of pharmacy, ATI, and NABP. I am confident that future discussions and meetings will occur as we share many common goals, and information requested by the state boards of pharmacy, ATI, and NABP will be provided to stakeholders interested in the certification of technicians.

If you have any questions, please feel free to contact me. Happy Holidays to you, your families, and staff.

cc: Steve Fredette, Chief Executive Officer, ATI  
 Rebecca Rabbit, Executive Director, Pharmacy Solutions  
 NABP Executive Committee



# Nevada State Board of Pharmacy

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## NEVADA STATE BOARD OF PHARMACY

### ACTIVITIES REPORT

#### DECEMBER 2<sup>ND</sup> & 3<sup>RD</sup>, 2009 BOARD MEETING HELD IN RENO, 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 December 2009 Board meeting.

#### Licensing Activity:

- 9 licenses were granted for Out-of-State pharmacies.
- 7 licenses were granted for Out-of-State MDEG companies.
- 10 licenses were granted for Out-of-State wholesalers.
- 7 licenses were granted for Nevada pharmacy (pending inspection).
- 1 license was granted for a Nevada manufacturer.

#### Disciplinary Action:

- One pharmaceutical technician was revoked for the diversion of controlled substances.
- Pharmacist DO's request for amending his disciplinary order to allow him to serve as a managing pharmacist was granted.
- Pharmacist VA was fined \$1700 for misfiling a prescription resulting in alleged patient harm, and for failure to counsel the patient.
- Pharmaceutical technician in training RM was granted registration after appearing to answer questions regarding a recent DUI.
- Pharmacist KO was fined \$1000 for misfiling a prescription resulting in alleged patient harm.
- Pharmacies WM and CP have been ordered to meet with Board Staff to discuss patient counseling problems and lack of required documentation.

#### Other Activity:

- Besides the usual business activities of the Board, a new treasurer was elected and discussions were held on issues ranging from prescription drug abuse to the scheduling of certain drugs.

### **Workshop:**

1. **Amendment of Nevada Administrative Code 639.945 Bona Fide Therapeutic Relationship**
2. **Amendment of Nevada Administrative Code AB213 Cancer Drug Donation Program.**
3. **Amendment of Nevada Administrative Code 639.7125 Use of fulfillment pharmacy by dispensing pharmacy.** Twofold: 1) To allow a registered mail order pharmacy to act as a fulfillment pharmacy, and 2) to better regulate and clarify the practices of a fulfillment pharmacy with respect to consumer understanding and patient safety.

### **Public Hearing:**

1. **Amendment of Nevada Administrative Codes 453.530 Schedule III and 453.550 Schedule V** The Board is removing buprenorphine from Schedule V (453.530) and adding buprenorphine to Schedule III (453.530) to parallel federal law.
2. **Amendment of Nevada Administrative Code 639.272 Requirements for Physicians Assistant registration.** This amendment will delete the requirement for a physician's assistant to have a relationship with a consultant pharmacist since they are already under the direct supervision of their collaborating physician.
3. **Amendment of Nevada Administrative Code 639.220 Schedule of Fees.** The language will increase the registration fee and renewal fee for pharmacists from \$150.00 to \$180.00 and the registration fee and renewal fee for intern pharmacists from \$15.00 to \$40.00. The Board has not increased fees for pharmacists since 2001 or for interns since 1995. The cost of doing business has increased, however by increasing these fees it will allow Board staff to continue to serve licensees in a professional timely manner.
4. **Amendment of Nevada Administrative Code 639.870 Requirements for Advanced Practitioner of Nursing registration.** This amendment will delete the requirement for an advanced practitioner of nursing to have a relationship with a consultant pharmacist since they are already under the direct supervision of their collaborating physician.



# DISCUSSION AND DETERMINATION

JANUARY 2010

## REFRIGERATOR LOG

Current Nevada statutes and regulations do not require a "refrigerator" or "temperature" log for refrigerators that contain pharmaceuticals. Should the Board consider such a regulation? Inspector Seidlinger has nicely outline the issue and has offered recommendations as follows:

- Several examples of issues - Please note the issue of out of range temperature readings in stores is not unusual:
  - Zostavax vaccine in a refrigerator and the refrigerator thermometer read 15 degrees F when Zostavax must be kept at 5 degrees or colder. The log had missing log dates and dates that showed improper storage temperatures. (the vaccine was removed for return/destruction)
  - Zostavax refrigerator with no temperature log (asked to remove and not utilize for immunizations)
  - On many inspections the refrigerator temperatures are at or below freezing (no temperature logs required for refrigerators that do not contain vaccines). One pharmacy today had 4 thermometers in the refrigerator with temperature readings of 38, 32, 32 and 28 degrees when I checked. There was not a daily temperature log. On opening insulin bottle packages (NPH) there was a precipitate on the bottle of the bottle. On the store inspection remarks I required the store to check all product in that refrigerator to ensure the medications are safe to dispense and segregate any product that there is any possibility of degradation.
  - Store with flu and pneumonia vaccine with the most current temperature log dated August and the logs were incomplete.
  - Many store's temperature logs are incomplete if kept at all.
  - Vaccine stored on top shelf near freezer against recommendations to prevent freezing.
  - Thermometers are often behind product where it is unlikely for staff to check temperature daily.
    - Stores may indicate on our inspection form that the temperature is checked daily but hidden thermometers lead me to believe this is not accurate
- Recommendations:
  - Requiring a temperature log will allow the inspectors to verify consistent, in range, storage temperatures within the pharmacy's refrigerators when inspecting.
  - People are creatures of habit, if the pharmacy team has to log refrigerator temperatures daily then the recording will become more consistent. If inspectors are reviewing logs there will be a greater focus on the requirement.
  - Stores that are closed some days of the week, need to have a thermometer in their medication refrigerators that will record temperatures on the days the store is closed for review and recording on the 1st day the store opens. I understand these are available at Home Depot, etc. for around \$20.
  - With the increase in pharmacists administering vaccines, biologicals, etc. (medications that can be very temperature fragile) the time has come to require documentation of refrigerator temperatures as added safety net for patient safety.

## **SCHEDULING OF PROPOFOL AS A CONTROLLED SUBSTANCE**

Since the Michael Jackson incident, there has been much discussion about scheduling propofol as a controlled substance. Propofol has been available in the US for medical use since 1989 and is currently not a controlled substance. Animal self-administration studies demonstrated that the reinforcing effects of the drug are relatively low. Staff took this question to the Controlled Substance Prescription Abuse Prevention Task Force (Task Force) last meeting, who after much discussion, recommended to not include it as a controlled substance, primarily due to low abuse potential.

Attached are several articles discussing propofol abuse, including a printout from the Department of Justice that has, as of September 2009, scheduled fospropofol as a CIV, even though they have not scheduled propofol. Fospropofol is metabolized to propofol which is the active metabolite. Go figure . . .

## Rules - 2009

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FR Doc E9-23971[Federal Register: October 6, 2009 (Volume 74, Number 192)] [Rules and Regulations] [Page 51234-51236] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr06oc09-3]

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### DEPARTMENT OF JUSTICE

#### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-327F]

#### Schedules of Controlled Substances; Placement of Fospropofol Into Schedule IV

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

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**SUMMARY:** With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance fospropofol, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule IV will be applicable to the manufacture, distribution, dispensing, importation, and exportation of fospropofol and products containing fospropofol.

**DATES:** Effective Date: November 5, 2009.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 307-7183.

#### SUPPLEMENTARY INFORMATION:

##### Background

On December 12, 2008, the Food and Drug Administration (FDA) approved fospropofol for marketing under the trade name Lusedra[reg] in the United States as a drug product indicated for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or

therapeutic procedures.

Fospropofol, 2,6-diisopropoxyphenoxymethyl phosphate disodium, is a water soluble, phosphono-O-methyl prodrug of propofol. It is metabolized in the body to propofol, the active metabolite. Propofol has been available for medical use in the United States since 1989 and is not currently a controlled substance. The pharmacological effects of fospropofol are attributed to the pharmacological actions of propofol. Propofol binds to [gamma]-aminobutyric acid (GABAA) receptor and acts as a modulator by potentiating the activity of GABA at this receptor.

Since propofol is the active metabolite of fospropofol, the abuse potential of fospropofol is comparable to that of propofol. Animal self-administration studies demonstrated that the reinforcing effects of propofol are relatively low and comparable to midazolam and other schedule IV benzodiazepines. Fospropofol elicits behavioral effects similar to methohexital and midazolam, schedule IV sedative-hypnotics.

Since fospropofol is a new molecular entity, there has been no evidence of diversion, abuse, or law enforcement encounters involving the drug.

On February 27, 2009, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that fospropofol be placed into schedule IV of the CSA. Enclosed with the February 27, 2009, letter was a document prepared by the FDA entitled, "Basis for the Recommendation for Control of Fospropofol and Its Salts in Schedule IV of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from DHHS, the Deputy Administrator of the DEA published a Notice of Proposed Rulemaking entitled "Schedules of Controlled Substances: Placement of Fospropofol into Schedule IV" on July 23, 2009 (74 FR 36424), which proposed placement of fospropofol into schedule IV of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before August 24, 2009.

#### Comments Received

The DEA received two comments in response to the Notice of Proposed Rulemaking. One comment received from a concerned citizen did not relate to fospropofol, the substance that is being controlled. Thus DEA did not consider this comment.

[[Page 51235]]

Another comment received from a professional organization of anesthesiologists is in agreement with the findings of scientific and medical evaluation that formed the basis for the present rule controlling fospropofol as a schedule IV substance and it fully supported this control action.

#### Scheduling of Fospropofol

Based on the recommendation of the Acting Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Fospropofol has a low potential for abuse relative to the drugs or substances in schedule III. Although there is no direct comparison to a schedule III substance, this finding is based on the demonstration of the abuse potential of propofol, the active metabolite, relative to the schedule IV substances, methohexital and midazolam;

(2) Fospropofol has a currently accepted medical use in treatment in the United States; and

(3) Abuse of fospropofol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III. This finding is based on the symptoms exhibited upon withdrawal from propofol.

Based on these findings, the Deputy Administrator of DEA concludes that fospropofol, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible warrants control in schedule IV of the CSA. (21 U.S.C. 812(b))

(4))

#### **Requirements for Handling Fospropofol**

**Registration.** Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with fospropofol, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with fospropofol, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before November 5, 2009 and may continue their activities until DEA has approved or denied that application.

**Security.** Fospropofol is subject to schedules III-V security requirements and must be manufactured, distributed, and stored in accordance with Sec. Sec. 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

**Labeling and Packaging.** All labels and labeling for commercial containers of fospropofol must comply with requirements of Sec. Sec. 1302.03-1302.07 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

**Inventory.** Every registrant required to keep records and who possesses any quantity of fospropofol must keep an inventory of all stocks of fospropofol on hand pursuant to Sec. Sec. 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on or after November 5, 2009. Every registrant who desires registration in schedule IV for fospropofol must conduct an inventory of all stocks of the substance on hand at the time of registration.

**Records.** All registrants must keep records pursuant to Sec. Sec. 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

**Prescriptions.** All prescriptions for fospropofol or prescriptions for products containing fospropofol must be issued pursuant to Sec. Sec. 1306.03-1306.06 and 1306.21, 1306.22-1306.27 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

**Importation and Exportation.** All importation and exportation of fospropofol must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

**Criminal Liability.** Any activity with fospropofol not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on or after November 5, 2009.

#### **Regulatory Certifications**

##### *Executive Order 12866*

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

##### *Regulatory Flexibility Act*

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Fospropofol products will be used for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures. Handlers of fospropofol also handle other controlled substances used for sedation which are already subject to the regulatory requirements of the CSA.

##### *Executive Order 12988*

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

*Executive Order 13132*

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

*Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

*Congressional Review Act*

This rule is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; Or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

0 Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28

[[Page 51236]]

CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

**PART 1308--SCHEDULES OF CONTROLLED SUBSTANCES**

- 1. The authority citation for 21 CFR part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

- 2. Section 1308.14 is amended in paragraph (c), by redesignating paragraphs (c)(23) through (c)(51) as paragraphs (c)(24) through (c)(52) and adding a new paragraph (c) (23) as follows:

**Sec. 1308.14 Schedule IV.**

\*\*\*\*\*

(c) \*\*\*

(23) Fospropofol..... 2138

\*\*\*\*\*

Dated: September 28, 2009.

**Michele M. Leonhart,**  
*Deputy Administrator.*

[FR Doc. E9-23971 Filed 10-5-09; 8:45 am]

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Monday September 14, 2009

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One of the reported deaths was a nurse anesthetist who died in January from self-administering propofol, says Lisa Thiemann, CRNA, senior director of professional practice for the AANA. Although the total number of healthcare professionals who abuse propofol is small, the deaths and the increased calls to the hotline prompted the association to develop a policy specific to the drug, she says.

According to AANA's warning statement, "At subanesthetic doses, feelings of elation and euphoria have been reported. Unfortunately, too often the first sign of propofol misuse or addiction is the practitioner's death."

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Propofol is not physically addicting, but can be psychologically addicting. Medical professionals don't usually take the drug to get high because it puts them instantly to sleep. Instead, it is taken to relieve stress because users wake up feeling refreshed, says Robert R. Kirby, MD, professor emeritus in the department of anesthesiology, University of Florida, College of Medicine, Gainesville. The drug also is popular because it has a rapid onset and short duration of action, he says.

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A similar survey has not been done of nurse anesthetists but the AANA is collating the information it receives from its hotline, says Zwerling.

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"Before 1992, clinicians and the manufacturer (of propofol) were convinced that such abuse was rare to nonexistent," Kirby, wrote in an article in the April 2009 issue of the *Anesthesia & Analgesia* about the use of propofol in homicide. "Since 1992, however, reports have been published [largely in forensic medical journals] concerning abuse, accidental overdose, and suicide."

Zwering says the warning signs for propofol abuse were there early on. Studies of propofol resulted in lab animals self-administering the medication because the drug had such a profound effect on the reward section of the brain, he says. "We went in knowing it had some addiction potential," Zwering says.

Patients who received the drug for surgical or endoscopic procedures also quickly realized the feel-good effects of propofol. "It was obvious this drug makes you feel really good," he says.

A fact sheet about propofol from the DEA notes, "Studies investigating the recovery profile of propofol have reported that patients anesthetized with propofol wake up 'elated,' 'euphoric,' and 'talkative.'"

Propofol is an effective anesthetic/sedative when administered by certified nurse anesthetists and anesthesiologists who have the appropriate resuscitative equipment nearby, Zwering says. Even physicians and nurses, except for ED doctors and ICU nurses, should not be administering propofol, says the AANA. "This is a drug that is extraordinarily dangerous in the wrong hands," he says.

Despite an apparent increase of propofol abuse, the DEA may still "decide not to schedule the drug because of its lesser potential for abuse," Payne says. It is unusual for a nonmedical person, such as Michael Jackson, to abuse propofol, say the anesthesia personnel interviewed. But the practice is beginning to infiltrate the population outside the medical community, say Zwering and Kirby.

Oxygen tanks and propofol were found in Jackson's home by police after his death and the drug was allegedly administered by his personal physician Conrad Murray, MD. Police believe Murray gave Jackson the propofol to help him sleep, although that is not a recognized use for the drug.

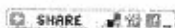
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However, a new form of propofol not yet on the market is much closer to being classified as a controlled substance and is in the public comments phase, says Payne. The drug, fospropofol (Lusedra), metabolizes into propofol once in the body. Fospropofol is water soluble and can be taken as a liquid, making it much easier to abuse than regular propofol, which must be administered intravenously. This is why the FDA recommended fospropofol be classified as a controlled substance, it says.

When propofol was introduced 20 years ago, "its potential for abuse was apparently not recognized from studies performed during development prior to its approval," the FDA said in a written statement. "Also, propofol is an injectable drug, not generally available to the public and used only for administration by anesthesiologists and other healthcare providers in hospitals and clinics in carrying out surgical procedures."

"Before 1992, clinicians and the manufacturer (of propofol) were convinced that such abuse was rare to nonexistent," Kirby, wrote in an article in the April 2009 issue of the *Anesthesia & Analgesia* about the use of propofol in homicide. "Since 1992, however, reports have been published [largely in forensic medical journals] concerning abuse, accidental overdose, and suicide."

Zwerling says the warning signs for propofol abuse were there early on. Studies of propofol resulted in lab animals self-administering the medication because the drug had such a profound effect on the reward section of the brain, he says. "We went in knowing it had some addiction potential," Zwerling says.

Patients who received the drug for surgical or endoscopic procedures also quickly realized the feel-good effects of propofol. "It was obvious this drug makes you feel really good," he says.

A fact sheet about propofol from the DEA notes, "Studies investigating the recovery profile of propofol have reported that patients anesthetized with propofol wake up 'elated,' 'euphoric,' and 'talkative.'"

Propofol is an effective anesthetic/sedative when administered by certified nurse anesthetists and anesthesiologists who have the appropriate resuscitative equipment nearby, Zwerling says. Even physicians and nurses, except for ED doctors and ICU nurses, should not be administering propofol, says the AANA. "This is a drug that is extraordinarily dangerous in the wrong hands," he says.

Despite an apparent increase of propofol abuse, the DEA may still "decide not to schedule the drug because of its lesser potential for abuse," Payne says. It is unusual for a nonmedical person, such as Michael Jackson, to abuse propofol, say the anesthesia personnel interviewed. But the practice is beginning to infiltrate the population outside the medical community, say Zwerling and Kirby.

Oxygen tanks and propofol were found in Jackson's home by police after his death and the drug was allegedly administered by his personal physician Conrad Murray, MD. Police believe Murray gave Jackson the propofol to help him sleep, although that is not a recognized use for the drug.

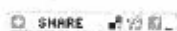
Jackson most likely became exposed to propofol during his cosmetic procedures and for surgery following a severe burn he received while filming a Pepsi commercial in the 1980s, says Zwerling.

*Janet Boivin, RN, is a senior writer at Gannett Healthcare Group.*

To comment, e-mail editorNT11@gannettthg.com.

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# THE WALL STREET JOURNAL.

WSJ.com

AUGUST 6, 2009

## Alert on M.D. Abuse Of Jackson Drug

By ALICIA MUNDY

Abuse of the sedative suspected in Michael Jackson's death is a growing problem among medical professionals, increasing pressure on the government to restrict it as a controlled substance.

Three days before the pop icon's death on June 25, the American Association of Nurse Anesthetists warned hospitals to restrict access to the potent drug **propofol** because some doctors and nurses are addicted to it.

Propofol, sold under the brand name Diprivan, is a widely used hospital sedatives. Because it is quick-acting and rapidly leaves the system, it is convenient for routine procedures such as same-day knee and cosmetic surgery, colonoscopies and bone repair.

The qualities that make propofol a popular sedative also make it a recreational drug for some in the medical profession. It doesn't show up in standard drug tests in the urine, and with a half-life of only five minutes, it doesn't leave the user groggy or affect behavior in a way that signals a substance-abuse problem.

The number of people with a propofol problem is small, and there is little data tracking addictions or death. A 2007 study covering 23,385 anesthesia personnel published in the journal *Anesthesia & Analgesia* by Paul Wischmeyer, a University of Colorado anesthesiologist, found

25 cases of propofol abuse over the preceding decade. The rate was a fivefold increase from a decade earlier. The study cited seven deaths. Dr. Wischmeyer and others in the field say that they know of other cases and estimate that the total number of deaths is at least several dozen in recent years.

"If you try to count backward from 100 after it's injected, you don't get to 97," says Dr. Wischmeyer. He and others say the drug is safe for hospital patients as long as a medical worker monitors "airway management" and provides oxygen as needed to ensure breathing doesn't stop.



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Getty Images

Michael Jackson at a press conference on March 5, 2009 in London, England.

Anesthetists and users say propofol can bring a brief but captivating high as the sedation wears off. Some call the habit, "dancing with a white rabbit," referring to the drug's color and hallucinogens of the 1960s. Others call it "pronapping," because the drug induces a short rest for medical personnel between long shifts.

Most medical centers don't lock up propofol or closely monitor inventory as they would for addictive painkillers such as Oxycontin. Propofol is readily accessible in most hospital supply rooms, sometimes along with Band-Aids and antibiotic ointments.

Paul Earley, medical director of Talbott Recovery Campus in Atlanta, which treats many medical professionals for substance abuse, said addictions to opiates and other drugs obscured the growing use of propofol.

"I was injecting it 50 times a day when I was in my worst period," says an anesthesiologist in the Midwest, who recently completed a stint in rehabilitation to kick the propofol habit. He said he began "pronapping" a couple of years ago while under stress from his job, family and finances. He hid the signs of shooting up by putting a port for a syringe on his leg, where it wasn't visible.

At night, he would inject the drug into the port in the bathroom, where his wife assumed he was brushing his teeth. "Sometimes it acted so fast, I couldn't get back to bed in time," said the anesthesiologist. He would pass out on the floor, terrifying his wife, and he said that on occasion he broke his nose or cheekbone or sprained a wrist.



After Mr. Jackson's death, police found propofol and oxygen tanks in his house, the Associated Press reported. Mr. Jackson's case would be rare, however. Almost all of the victims of propofol addiction and overdose are medical professionals, particularly anesthesia providers, experts say. The drug isn't generally available outside hospitals and clinics.

Drug abuse among medical professionals has received growing attention over the years, prompting some states to develop prevention and treatment programs. Long shifts and stressful life-and-death cases, as well as ready access to dangerous drugs, have all fueled the problem, say rehabilitation experts.

Propofol is so potent that a tiny amount -- 20 milligrams -- can be the difference between rest and death. "It enters your bloodstream fast, and even highly trained anesthesiologists can't control it, and die. They don't even have seconds to pull out the needle," said Art Zwerling, a registered nurse anesthetist and counselor with the Association of Nurse Anesthetists, a 39,000-member group.

Teva Pharmaceuticals Ltd., which makes generic propofol, and APP Pharmaceuticals Inc., which sells the drug under the Diprivan name, said separately that the drug is safe when used as directed in proper settings.

Propofol was never classified as a controlled substance by the Drug Enforcement Administration when it was first approved 20 years ago, nor was it recommended for that status by the Food and Drug Administration. Two years ago, a citizen petition was filed at the DEA, asking that propofol be designated a controlled substance, which requires an FDA recommendation. Representatives of both agencies said they've been reviewing the matter. One official said a decision could come in a few months.

An FDA spokeswoman said since Mr. Jackson's death, the agency has received many questions from doctors and the public about when and whether it will decide to classify propofol.

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Making propofol a controlled substance under DEA rules would require hospitals to track inventory, account for all vials, list users, and lock it up with narcotics. That is not popular with many anesthesiology providers, and a poll by Anesthesiology News taken after Mr. Jackson's death found that 61% of them oppose it.

Several anesthesiologists and nurse anesthetists say that because propofol is an important drug for use in emergencies, it must be kept handy. In some cases, a surgeon may suddenly need more propofol to keep a patient sedated, and a few seconds' delay makes a difference. They favor hospitals taking voluntary steps to control inventory.

Another concern: Tighter regulation might impede doctors and nurses from seeking help for addiction, because abusing a DEA-controlled drug is more likely to cost them their licenses and lead to criminal charges.

Clarence Ward, a California anesthesiologist, wrote in a 2008 article in the California Society of Anesthesiologists bulletin, that too many doctors don't acknowledge abuse. In an interview, he said people die "not necessarily from intent, but from an inability to control a drug that causes abrupt loss of consciousness."

Write to Alicia Mundy at [alicia.mundy@wsj.com](mailto:alicia.mundy@wsj.com)  
Printed in The Wall Street Journal, page A1

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# British Journal of Anaesthesia

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## Death related to a recreational abuse of propofol at therapeutic dose range

Editor—We report the case of a 27-yr-old male anaesthetic nurse found dead at home after self administration of propofol, for recreational purpose. He had several puncture wounds suggesting a chronic abuse during the preceding days. Three empty ampoules of propofol of 20 ml (10 mg ml<sup>-1</sup>) were discovered beside him and unused ampoules were found in his car.

Toxicological analysis detected propofol in blood, bile and urine by gas chromatography/mass spectrometry. These propofol concentrations were within therapeutic range [blood (0.026 µg ml<sup>-1</sup>) and bile (0.25 µg ml<sup>-1</sup>)]. Lidocaine was identified in the blood at a subtherapeutic concentration (1.5 µg ml<sup>-1</sup>) by liquid chromatography/diode array detection. A lidocaine spray found beside him may have been used to avoid pain during the placement of the intubation tube. No other substances were detected.

Forensic investigation found acute pulmonary oedema and haemorrhagic pancreatitis, two rare propofol-induced adverse drug reactions.<sup>1,2</sup> It is well known that propofol administration, even at therapeutic dose, can cause respiratory depression.<sup>2</sup> In this case, death could have occurred as result of a pulmonary oedema as he did not receive ventilatory or medical assistance.

Euphoria, sexual hallucinations and disinhibition have been described on recovery of propofol anaesthesia.<sup>1,2</sup> These effects could explain the recreational use of the drug. Moreover, several

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experimental studies strongly suggest the potential for abuse and dependence on propofol,<sup>3–5</sup> and few cases of abuse and dependency have been described, mostly in medical professionals. As propofol is generally not recognized as a substance of abuse, and because of its safe profile, it is important to remember that rare adverse reactions of propofol could produce death in a context of abuse, even at therapeutic dose range, in the absence of ventilatory and medical assistance.




**A. Roussin\*, M. Mirepoix, G. Lassabe, V. Dumestre-Toulet, V. Gardette, J.-L. Montastruc and M. Lapeyre-Mestre**

*Toulouse, France*

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## **SCHEDULING OF LISDEXAMFETAMINE, LACOSAMIDE AND TAPENTADOL AS CONTROLLED SUBSTANCES**

Request from METRO Sheriff Gillespie (see attached).



November 16, 2009

LARRY PINSON  
NEVADA STATE BOARD OF PHARMACY  
431 PLUMB LN  
RENO NV 89509

Dear Mr. Pinson:

The Drug Enforcement Administration (DEA) amended the Controlled Substances Act by adding the following substances: (See attached copies of the Federal Register)

1. Lisdexamfetamine - Schedule II effective June 4, 2007, published in Vol.72 No.85 Pg. 24532
2. Lacosamide - Schedule V effective June 22, 2009, published in Vol. 74 No.97 Pg.23789
3. Tapentadol - Schedule II effective June 22, 2009, published in Vol. 74 No. 97 Pg.23790

These substances are not currently listed in the Nevada Administrative code (NAC) chapter 453 list of controlled substances. Pursuant to Nevada Revised Statute (NRS) 453.2182, substances which are controlled by federal law can be adopted by the Nevada State Board of Pharmacy for inclusion in the NAC. Please present these substances for scheduling to the Nevada State Pharmacy Board at their next meeting. This would bring the NAC into agreement with federal scheduling laws. Please let me know if I can be of further assistance.

Sincerely,

Doug Gillespie, SHERIFF

BY: Tracy H. Birch  
Forensic Lab Manager  
Las Vegas Metro Police Dept.  
5605 W Badura # 120B  
Las Vegas, NV 89118  
(702) 828-3945

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[Federal Register: May 3, 2007 (Volume 72, Number 85)]  
[Rules and Regulations]  
[Page 24532-24534]  
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-301F]

Schedules of Controlled Substances: Placement of **Lisdexamfetamine**  
Into Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final Rule.

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SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance lisdexamfetamine, including its salts, isomers and salts of isomers into schedule II of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule II will be applicable to the manufacture, distribution, dispensing, importation and exportation of lisdexamfetamine and products containing lisdexamfetamine.

EFFECTIVE DATE: June 4, 2007.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, (202) 307-7183.

SUPPLEMENTARY INFORMATION: Lisdexamfetamine is a central nervous system stimulant drug. On February 23, 2007, the Food and Drug Administration (FDA) approved lisdexamfetamine for marketing under the trade name Vyvanse™. Lisdexamfetamine will be marketed as a prescription drug product for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Lisdexamfetamine is an amide ester conjugate comprised of the amino acid L-lysine covalently bound to the amino group of d-amphetamine. The chemical name of its dimesylate salt form is (2S)-2,6-diamino-N-[(1S)-1-methyl-2-phenethyl]hexanamide dimethanesulfonate (CAS number 608137-32-3). Lisdexamfetamine per se is pharmacologically inactive and its effects are due to its in vivo metabolic conversion to d-amphetamine.

Lisdexamfetamine is a new molecular entity and has not been marketed in the United States or other countries. Therefore, there has been no evidence of diversion, abuse, or law enforcement encounters involving lisdexamfetamine.

On November 14, 2006, the Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy

Administrator of DEA a scientific and medical evaluation and a letter recommending that lisdexamfetamine be placed into schedule II of the CSA. Enclosed with the November 14, 2006, letter was a document prepared by the FDA entitled, ``Basis for the Recommendation for Control of Lisdexamfetamine in Schedule II of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation received from DHHS, the Deputy Administrator of the DEA, in a February 22, 2007, Notice of Proposed Rulemaking (72 FR 7945), proposed placement of lisdexamfetamine into schedule II of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments to be postmarked and electronic comments be sent on or before March 26, 2007.

#### Comments Received

The DEA received two comments in response to the Notice of Proposed Rulemaking. One commenter stated that monthly visits to obtain refills for Concerta [supreg]--like drugs used in children are very expensive and the law needs to be changed. DEA notes that statutory requirements for schedule II drugs do not permit prescription refills. DEA does not regulate the size of each prescription or the frequency of medical visits; these matters are within the purview of prescribing physician. DEA has no authority regarding either the cost of medical care or the cost of the medications a prescribing practitioner may prescribe. Another commenter requested the name of the company that filed the New Drug Application for lisdexamfetamine in order to obtain standard analytical reference material and/or analytical data from the company. This comment is not relevant to the present scheduling action.

#### Scheduling of Lisdexamfetamine

Relying on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in response to the Notice of Proposed Rulemaking, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

[[Page 24533]]

- (1) Lisdexamfetamine has a high potential for abuse;
- (2) Lisdexamfetamine has a currently accepted medical use in treatment in the United States; and
- (3) Abuse of lisdexamfetamine may lead to severe psychological or physical dependence.

Based on these findings, the Deputy Administrator of DEA concludes that lisdexamfetamine, including its salts, isomers, and salts of isomers, warrants control in schedule II of the CSA. The applicable regulations are as follows:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with lisdexamfetamine, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with lisdexamfetamine, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations. Any person who is

currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before June 4, 2007 and may continue their activities until DEA has approved or denied that application.

**Security.** Lisdexamfetamine is subject to schedule II security requirements and must be manufactured, distributed and stored in accordance with Sec. Sec. 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76 and 1301.77 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Labeling and Packaging.** All labels and labeling for commercial containers of lisdexamfetamine must comply with requirements of Sec. Sec. 1302.03-1302.07 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Quotas.** Quotas for lisdexamfetamine must be established pursuant to part 1303 of Title 21 of the Code of Federal Regulations.

**Inventory.** Every registrant required to keep records and who possesses any quantity of lisdexamfetamine must keep an inventory of all stocks of lisdexamfetamine on hand pursuant to Sec. Sec. 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on or after June 4, 2007. Every registrant who desires registration in schedule II for lisdexamfetamine must conduct an inventory of all stocks of the substance on hand at the time of registration.

**Records.** All registrants must keep records pursuant to Sec. Sec. 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Reports.** All registrants required to submit reports to the Automation of Reports and Consolidated Order System (ARCOS) in accordance with Sec. 1304.33 of Title 21 of the Code of Federal Regulations must do so for lisdexamfetamine.

**Orders for Lisdexamfetamine.** All registrants involved in the distribution of lisdexamfetamine must comply with the order requirements of part 1305 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Prescriptions.** All prescriptions for lisdexamfetamine or prescriptions for products containing lisdexamfetamine must be issued pursuant to 21 CFR 1306.03-1306.06 and 1306.11-1306.15.

**Importation and Exportation.** All importation and exportation of lisdexamfetamine must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Criminal Liability.** Any activity with lisdexamfetamine not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on or after June 4, 2007.

## Regulatory Certifications

### Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ``on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

## Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and by approving it certifies that it will not have a significant economic

impact on a substantial number of small entities. Lisdexamfetamine products will be prescription drugs used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Handlers of lisdexamfetamine also handle other controlled substances used to treat ADHD which are already subject to the regulatory requirements of the CSA.

#### Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

#### Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

#### Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

#### Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

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Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

#### PART 1308--SCHEDULES OF CONTROLLED SUBSTANCES

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1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

0

2. Section 1308.12 is amended by adding a new paragraph (d)(5) to read as follows:

Sec. 1308.12 Schedule II.

\* \* \* \* \*

(d) \* \* \*

[[Page 24534]]

(5) Lisdexamfetamine, its salts, isomers, and salts of its isomers--1205.

\* \* \* \* \*

Dated: April 25, 2007.

Michele M. Leonhart,  
Deputy Administrator.

[FR Doc. E7-8421 Filed 5-2-07; 8:45 am]

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[Federal Register: May 21, 2009 (Volume 74, Number 97)]  
[Rules and Regulations]  
[Page 23789-23790]  
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[[Page 23789]]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-325F]

Schedules of Controlled Substances: Placement of Lacosamide into Schedule V

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

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SUMMARY: With the issuance of this final rule, the Deputy Administrator of the DEA places the substance lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide] and any material, compound, mixture, or preparation which contains any quantity of lacosamide into schedule V of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule V will be applicable to the manufacture, distribution, dispensing, importation and exportation of lacosamide.

DATES: Effective Date: This rule is effective June 22, 2009.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug

Enforcement Administration, 8701 Morrisette Drive, Springfield, VA  
22152, (202) 307-7183.

#### SUPPLEMENTARY INFORMATION:

##### Background

On October 28, 2008, the Food and Drug Administration (FDA) approved lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide] for marketing under the trade name Vimpat[supreg] for use as an adjunctive therapy in treatment of partial-onset seizures in patients with epilepsy ages 17 years and older.

On December 2, 2008, the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) sent the Administrator of the DEA a scientific and medical evaluation and a letter recommending that lacosamide be placed into schedule V of the CSA. Enclosed with the December 2, 2008, letter was a document prepared by the FDA entitled ``Basis for the Recommendation for Control of Lacosamide in Schedule V of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

Based on the recommendation of the Assistant Secretary for Health and an independent review of the available data by the DEA, the Deputy Administrator of the DEA, in a March 10, 2009, Notice of Proposed Rulemaking (74 FR 10205) proposed placement of lacosamide into schedule V of the CSA. The proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing to be received by the DEA on or before April 9, 2009.

##### Comments Received

DEA received one comment within the comment period in response to the Notice of Proposed Rulemaking. The commenter stated that lack of information and inappropriate comparisons to other drugs precluded the scheduling of lacosamide and suggested that scheduling be postponed for 24 months to collect data.

DEA does not agree. The studies used to assess abuse potential of lacosamide are widely held as the standard methods of evaluation. Behavioral effects of lacosamide in animals and humans were found to be similar to, but transient relative to, those of the schedule IV drugs alprazolam and phenobarbital. Preclinical studies indicated that lacosamide is self-administered at rates higher than saline and partially mimics discriminative stimulus effects to the schedule IV substances alprazolam and phenobarbital. In clinical trials, lacosamide produced subjective responses similar to alprazolam but these effects did not last as long as alprazolam. After careful consideration of positive indicators from preclinical and clinical studies, DEA finds lacosamide has abuse potential supporting placement in schedule V under the CSA. The DHHS recommended control in schedule V of the CSA and the DEA concurs.

The commenter also submitted a request for a hearing. DEA regulations provide that ``[a]ny interested person'' may request a hearing on a proposed scheduling action. 21 CFR 1308.44(a). DEA regulations define ``interested person'' as ``any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. 811].'' 21 CFR 1300.01(b)(19). The regulations further require that any person requesting a hearing must state ``with particularity'' his interest in the proceeding. 21 CFR 1316.47(a). The commenter failed to provide sufficient information to demonstrate that he meets the definition of ``interested person'' as set forth in the

regulations, therefore DEA is denying his hearing request.

DEA also received many comments after the comment period closed. These late comments were not considered by DEA.

#### Scheduling of Lacosamide

Based on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by the DEA, the Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

- (1) Lacosamide has a low potential for abuse relative to the drugs or other substances in schedule IV;
- (2) Lacosamide has a currently accepted medical use in treatment in the United States; and
- (3) Abuse of lacosamide may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

Based on these findings, the Deputy Administrator of the DEA concludes that lacosamide and any material, compound, mixture, or preparation which contains any quantity of lacosamide, warrant control in schedule V of the CSA.

#### Requirements for Handling Lacosamide

Registration. Any person who manufactures, distributes, dispenses, [[Page 23790]]

imports, exports, engages in research or conducts instructional activities with lacosamide, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with lacosamide, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations (CFR). Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before June 22, 2009 and may continue their activities until the DEA has approved or denied the application.

Security. Lacosamide is subject to schedule III-V security requirements and must be manufactured, distributed, and stored in accordance with Sec. Sec. 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 of Title 21 of the CFR on and after June 22, 2009.

Labeling and Packaging. All labels and labeling for commercial containers of lacosamide which are distributed on or after June 22, 2009 must comply with requirements of Sec. Sec. 1302.03-1302.07 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of lacosamide must keep an inventory of all stocks of lacosamide on hand pursuant to Sec. Sec. 1304.03, 1304.04 and 1304.11 of Title 21 of the CFR on or after June 22, 2009. Every registrant who desires registration in schedule V for lacosamide must conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to Sec. Sec. 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

Prescriptions. All prescriptions for lacosamide pharmaceutical

products must be issued pursuant to 21 CFR 1306.03-1306.06 and 1306.21, 1306.23-1306.27 on or after June 22, 2009.

Importation and Exportation. All importation and exportation of lacosamide must be in compliance with part 1312 of Title 21 of the CFR on or after June 22, 2009.

Criminal Liability. Any activity with lacosamide not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act occurring on or after June 22, 2009 shall be unlawful.

#### Regulatory Certifications

##### Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ``on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, Sec. 3(d)(1).

#### Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Lacosamide pharmaceutical products will be prescription drugs used for the treatment of partial-onset seizures. Handlers of lacosamide often handle other controlled substances used in the treatment of central nervous system disorders which are already subject to the regulatory requirements of the CSA.

##### Executive Order 12988

This regulation meets the applicable standards set forth in Sec. Sec. 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

##### Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

#### Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

#### Congressional Review Act

This rule is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the

economy of \$100,000,000 or more; a major increase in costs or prices: or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

#### List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

0

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to Title 28, Part 0, Appendix to Subpart R, Section 12, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

#### PART 1308--SCHEDULES OF CONTROLLED SUBSTANCES

0

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

0

2. Section 1308.15 is amended by revising paragraph (e)(1) and adding a new paragraph (e)(2) to read as follows:

#### Sec. 1308.15 Schedule V.

\* \* \* \* \*

(e) \* \* \*

(1) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide]--  
2746

(2) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid]--2782

Dated: May 12, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9-11927 Filed 5-20-09; 8:45 am]

BILLING CODE 4410-09-P

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[Federal Register: May 21, 2009 (Volume 74, Number 97)]  
[Rules and Regulations]  
[Page 23790-23793]  
From the Federal Register Online via GPO Access [wais.access.gpo.gov]  
[DOCID:fr21my09-2]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-319F]

Schedules of Controlled Substances: Placement of Tapentadol Into  
Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

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SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance tapentadol, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, into schedule II of the

[[Page 23791]]

Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule II will be applicable to the manufacture, distribution, dispensing, importation, and exportation of tapentadol and products containing tapentadol.

DATES: Effective Date: June 22, 2009.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Background

On November 20, 2008, the Food and Drug Administration (FDA) approved tapentadol for marketing in the United States as a prescription drug product for the treatment of moderate-to-severe acute pain. Tapentadol is a new molecular entity with centrally-acting analgesic properties.

Tapentadol has dual modes of action, namely mu ([mu]) opioid receptor agonistic action and inhibition of reuptake of norepinephrine at the norepinephrine transporter. The chemical name of its monohydrochloride salt form is 3-[(1R,2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl]phenol hydrochloride. Tapentadol shares substantial

pharmacological effects and abuse potential with other schedule II opioid analgesics, e.g., morphine, oxycodone, and hydromorphone.

Since tapentadol is a new molecular entity, there has been no evidence of diversion, abuse, or law enforcement encounters involving the drug.

On November 13, 2008, the Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that tapentadol be placed into schedule II of the CSA. Enclosed with the November 13, 2008, letter was a document prepared by the Food and Drug Administration (FDA) entitled, ``Basis for the Recommendation for Control of Tapentadol in Schedule II of the Controlled Substances Act.'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from DHHS, the Deputy Administrator of the DEA published a Notice of Proposed Rulemaking entitled ``Schedules of Controlled Substances: Placement of Tapentadol into Schedule II'' on February 17, 2009 (74 FR 7386), which proposed placement of tapentadol into schedule II of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before March 19, 2009.

#### Comments Received

The DEA received three comments in response to the Notice of Proposed Rulemaking. One comment was from a consulting firm, one comment was from a concerned citizen, and the last comment was from a company which does research and development on pharmaceutical drugs.

The first commenter recommended that the DEA expedite the issuance and effective date of the Final Rule placing tapentadol in schedule II. The commenter stated that tapentadol will provide a safe and effective substitute for other schedule II analgesics and that the conditions of public health necessitate and justify this request. In response, DEA believes that providing 30 days for this rule to become effective is both expeditious and sufficient to allow handlers to apply for registration with DEA and to comply with the regulatory requirements for handling schedule II controlled substances.

A second commenter stated that since tapentadol induces effects similar to oxycodone and morphine, both schedule II substances, then it should be placed in schedule II of the Controlled Substances Act based on tapentadol's abuse potential. Thus, the commenter agreed with DHHS' recommendation and the action proposed by DEA. No response from DEA is necessary to this comment because it is consistent with the DEA's final action.

The third commenter had four questions/comments regarding the implementation of this Final Rule. Each question/comment is addressed below.

The commenter requested that DEA registrants be allowed enough time to make the changes needed to carry out handling tapentadol as a schedule II substance, as dictated in 21 CFR 1301.51, 1301.71, and 1304.04. In response to this comment, the effective date of the Final Rule placing tapentadol in schedule II of the Controlled Substances Act will be thirty (30) days from the date of publication of the Final Rule, thus allowing ample time for those that wish to handle tapentadol to meet DEA regulatory requirements for handling schedule II substances. It has been DEA's experience that this is sufficient time to meet the regulatory requirements provided below.

The commenter asked if quantities of tapentadol held by a DEA



registrant would have to be reported once the scheduling of tapentadol as a schedule II substance was finalized. In response, the reporting and recordkeeping requirements for handling schedule II substances can be found in 21 CFR part 1304. Specifically, 21 CFR 1304.11(b) states that ``Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances \* \* \*'' In order for a manufacturer to handle a schedule II substance, a manufacturing or procurement quota has to be requested in accordance with the requirements of 21 U.S.C. 826(c) and 21 CFR part 1303. The manufacturer's inventory of the substance is used, in part, to determine the manufacturer's quota.

The commenter asked about the process for adding the CSA drug code for tapentadol to their registration. In response, the regulatory process required to obtain a DEA registration is outlined generally in 21 CFR 1301.11 through 1301.19, and the process required to modify an existing DEA registration is outlined in 21 CFR 1301.51. Information relating to registration may be found on the Internet, <http://www.DEAdiversion.usdoj.gov>, or by contacting DEA's Registration Call Center, toll free at 1-800-882-9539.

Finally, the commenter inquired about the process for establishing an NDC number for tapentadol with the Automation of Reports and Consolidated Orders System (ARCOS). National Drug Code (NDC) numbers are assigned by the Food and Drug Administration (FDA) in conjunction with registration and drug listing requirements of the Federal Food, Drug, and Cosmetic Act. Accordingly, a person manufacturing a product containing tapentadol must obtain an NDC number from FDA in accordance with 21 CFR 207.35. Once the drug code for tapentadol is added to an existing manufacturer's registration or a new registration is issued to an applicant, then that DEA-registered manufacturer must provide the DEA's ARCOS Unit with its established NDC number for their product containing tapentadol. Once that information is obtained, it can be used to report ARCOS reportable transactions pursuant to 21 CFR 1304.33.

#### Scheduling of Tapentadol

Based on the recommendation of the Assistant Secretary for Health, received

[[Page 23792]]

in accordance with Sec. 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in response to the Notice of Proposed Rulemaking, the Deputy Administrator of DEA, pursuant to Sec. Sec. 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

- (1) Tapentadol has a high potential for abuse;
- (2) Tapentadol has a currently accepted medical use in treatment in the United States; and
- (3) Abuse of tapentadol may lead to severe psychological or physical dependence.

Based on these findings, the Deputy Administrator of DEA concludes that tapentadol, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, warrants control in schedule II of the CSA (21 U.S.C. 812(b)(2)).

#### Requirements for Handling Tapentadol

**Registration.** Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with tapentadol, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with tapentadol, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before June 22, 2009 and may continue their activities until DEA has approved or denied that application.

**Security.** Tapentadol is subject to schedule II security requirements and must be manufactured, distributed, and stored in accordance with Sec. Sec. 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76 and 1301.77 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

**Labeling and Packaging.** All labels and labeling for commercial containers of tapentadol must comply with requirements of Sec. Sec. 1302.03 through 1302.07 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

**Quotas.** Quotas for tapentadol must be established pursuant to part 1303 of Title 21 of the Code of Federal Regulations.

**Inventory.** Every registrant required to keep records and who possesses any quantity of tapentadol must keep an inventory of all stocks of tapentadol on hand pursuant to Sec. Sec. 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on or after June 22, 2009. Every registrant who desires registration in schedule II for tapentadol must conduct an inventory of all stocks of the substance on hand at the time of registration.

**Records.** All registrants must keep records pursuant to Sec. Sec. 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

**Reports.** All registrants required to submit reports to the Automation of Reports and Consolidated Order System (ARCOS) in accordance with Sec. 1304.33 of Title 21 of the Code of Federal Regulations must do so for tapentadol.

**Orders for Tapentadol.** All registrants involved in the distribution of tapentadol must comply with the order form requirements of part 1305 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

**Prescriptions.** All prescriptions for tapentadol or prescriptions for products containing tapentadol must be issued pursuant to Sec. Sec. 1306.03 through 1306.06 and 1306.11 through 1306.15 of Title 21 of the Code of Federal Regulations on and after June 22, 2009.

**Importation and Exportation.** All importation and exportation of tapentadol must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

**Criminal Liability.** Any activity with tapentadol not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful on or after June 22, 2009.

## Regulatory Certifications

### Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ``on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

## Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Tapentadol products will be prescription drugs used for the treatment of moderate-to-severe acute pain. Handlers of tapentadol also handle other controlled substances used to treat pain which are already subject to the regulatory requirements of the CSA.

## Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

## Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

## Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and Tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

## Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

## List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

0

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to Title 28, Part 0, Appendix to Subpart R, Section 12, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

[[Page 23793]]

PART 1308--SCHEDULES OF CONTROLLED SUBSTANCES

0

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

0

2. Section 1308.12 is amended in the table by adding a new paragraph (c)(28) to read as follows:

Sec. 1308.12 Schedule II.

\* \* \* \* \*

(c) \* \* \*

(28) Tapentadol..... 9780

\* \* \* \* \*

Dated: May 15, 2009.  
Michele M. Leonhart,  
Deputy Administrator.  
[FR Doc. E9-11933 Filed 5-20-09; 8:45 am]  
BILLING CODE 4410-09-P

## DISCUSSION ON PATIENT COUNSELING

Mr. Macdonald requested a discussion of patient counseling to include input from our inspectors and investigators. All will be present. Some background and considerations:

OBRA-90 (enacted in 1990) has made counseling of new prescriptions for Medicaid patients by a pharmacist, a requirement for some twenty years now. The Nevada Legislature quickly adopted NRS 639.266 making counseling by a pharmacist a requirement of **all** new prescriptions, not just Medicaid prescriptions.

The above mentioned statute required the Board of Pharmacy to then adopt regulations to define the elements of counseling (NAC 639.700, NAC 639.707, & NAC 639.708). The resulting regulations basically require the following:

- A pharmacist must counsel all new prescriptions
- A pharmacist must document that counseling
- A pharmacist must document a patient's refusal to accept counseling

Our Board inspectors always have, and will continue, to inspect to the law, including our counseling laws. It is obvious to staff that many pharmacies in Nevada simply are not counseling, or do it minimally. This becomes apparent as we bring cases such as a 2 y/o receiving Septra-DS tablets and a patient receiving an antipsychotic rather than her prescribed fertility drug, both marked "counseled" by the pharmacist. Rest assured that in any case involving a misfill, mislabel, ingestion of a wrong medication, a patient getting another patient's medication, etc., the counseling log will be investigated.

Quality of counseling has emerged as an issue with the increasing demands on pharmacists working in busy pharmacies. Our regulations were recently changed to "soften" what the pharmacist "must" provide to the patient in lieu of using his professional judgment in what counseling points "may" be offered.

Attached for your perusal is a November, 2009, article from the Los Angeles Times on pharmacist counseling provided by Ms. Lau as well as a Supreme Court Ruling on a pharmacy's duty to warn distributed by Mr. Macdonald in 2002.

Board staff is and has been proud of our Board's long standing stance on the importance of counseling. There is no question that patient counseling by the pharmacist provides the best patient care and is paramount in the prevention of prescription errors. It is the pharmacist's last chance to ensure that the prescription is correct and that the patient understands how to take it. Finally, and most important to many, is the fact that counseling is really the only thing left for a pharmacist to do. Technology and technicians can fill prescriptions; a pharmacist is no longer necessary other than for a final check, as mail order, hospital robotics, fulfillment centers and workload sharing have demonstrated. If the pharmacist gives up that final and most important function unique to his profession, the profession will fade.

Board staff also reminds the Board of their primary purpose of existence, that being for the protection of the public by ensuring the best possible pharmaceutical care for Nevadans. The Board does not exist for the protection of the pharmacist or the pharmacy. It is no secret that many pharmacies are extremely busy, but that is not the fault of the patient. A patient's care should not be compromised simply because a pharmacy gets busy. Maybe staffing should be examined.

A reminder: The "disciplinary matrix" is nothing more than a guideline. You, as the Board, are not limited by the matrix, staff is. You can rule, fine, dismiss, add probation, require CE, etc. as you deem appropriate. Staff uses the matrix only as a template to charge cases and to offer some consistency in your rulings.

#### Food for Thought:

- Should there be minimum requirements for how many prescriptions a pharmacist can be responsible for, to allow ample counseling time rather than adjusting regulations to fit the pharmacist's workload?
- Should pharmacies be required to staff a "counseling pharmacist" when they reach a point of inadequate counseling due to sheer numbers, whose only job would be to counsel patients?
- What constitutes adequate counseling and who makes that judgment? (the Board; the courts?)
- Are computer systems with "time clocks", said to be there for the pharmacist to better judge his workload, really in the patient's best interest?
- Our regulations contemplate documenting counseling (or refusal) immediately after said task. Is it reasonable to allow that documentation some time after the activity, and if so, how long after? How does the pharmacist remember who he has counseled or who refused, when he documents at some later time? Isn't that documentation probably the pharmacist's most important step for his own protection, given a hearing some months after an incident when he cannot recall that specific activity?
- Obviously, no two computer systems are alike. Should the Board consider some sort of standardization for counseling? Documentation issues seem to have surfaced as we have shifted away from paper logs. Is a paper log really that bad?
- Often the patient claims that they were not counseled and the pharmacist states otherwise and no documentation of either counseling or refusal exists. Who do you believe? What about when the counseling log is marked "refused" and the patient does not recall refusing?
- How does staff deal with counseling logs that indicate often 80% "refusal"? Is the patient really "refusing" or are they deeming "refusing" by signing something they have not read or do not understand?

- How does a pharmacy ensure that a patient does not leave the pharmacy with a new prescription that has not been counseled or refused? Should the Board mandate who actually hands the drug to the patient in the end?
- Knowing that counseling provides the best patient care and helps catch prescription errors, how would softening counseling regulations benefit the patient?

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## **FW: Pharmacists are a vital, if under-used, part of healthcare**

Mary Lau [MaryLau@rannv.org]

**Sent:** Monday, November 30, 2009 11:11 AM

**To:** LARRY L. PINSON; Chad Leubke [cmluebke@cvs.com]; Keith Macdonald [gmacrex79@charter.net]; kam.gandhi@albertsons.com; Donald Fey [Donald.Fey@HCAHealthcare.com]

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**latimes.com**

### **Pharmacists are a vital, if under-used, part of healthcare One physician says their years of training make them 'walking encyclopedias' on drug effectiveness, side effects and interactions.**

By Karen Ravn

November 30, 2009

There's an old Jerry Seinfeld joke many pharmacists know all too well. It's the one in which he describes their "whole job" as taking pills from a big bottle and putting them in a little bottle.

"I think that's how a lot of people see us," says Jeff Goad, an associate professor at the USC School of Pharmacy, with both frustration and good humor.

But pharmacists' long years of training -- at least six and as many as eight -- prepare them for much more than repackaging pills. "In terms of the number of hours spent studying drug effectiveness, pharmacists are better trained than physicians," says Julie Donohue, an associate professor of health policy and management at the University of Pittsburgh.

Gone are the days in which pharmacists wouldn't even tell patients what was in their medications, Goad says. Pharmacists now can help patients get the most good from their medications, manage side effects, avoid interactions, even save money.

Today, most, if not all, states have laws requiring pharmacists to give patients specific information. Pharmacists in California are required by state law to offer counseling to patients about every new or changed prescription they fill. Pharmacists and other public health experts call this an offer no one should refuse. **"It's the last critical safety check,"** Goad says.

**Too often, this safety check doesn't happen.**

**Many customers sign away their right to the service.** In 2004 and 2005, the Center for Health

Improvement, an independent nonprofit health policy organization based in Sacramento, examined the prescription counseling process in California for patients 65 and older. The statewide survey of pharmacists found that 50% of patients waived counseling either "sometimes," "often" or "always."

Some patients are in a hurry. Or they're embarrassed. Or they don't want to bother the pharmacist. Or they'd rather just read the written information that pharmacists are required to give (though it's not clear how often -- or how well -- they really do read it).

Some turn down counseling without even knowing it, simply by signing a form that their pharmacists (or maybe the pharmacists' assistants or clerks) hand them with no explanation.

"Good pharmacists should almost force themselves on patients," says Steven Chen, associate professor at the USC School of Pharmacy. "They should definitely never say, 'If you don't want counseling, just sign this line.' But that happens with too many pharmacists."

### Warning signs

California law specifies the basic format for prescription counseling: One, pharmacists should give patients directions for how to use and store their medications, making clear that it's important to follow those directions. And two, they should warn patients about possible side effects or interactions that occur frequently and may be severe. Other issues to be discussed are optional, left to the pharmacist's discretion.

The Center for Health Improvement study found that even the required elements are sometimes given short shrift. When asked about an average counseling session with senior patients, 93% of pharmacists said they "often" or "always" gave directions for medication usage (though only 81% said they "often" or "always" discussed how important it was to follow the directions), and 87% said they "often" or "always" gave appropriate warnings.

Pharmacists were much less likely to cover optional issues. For example, only 39% said they "often" or "always" discussed what patients should do if they miss a dose of their medication.

More than 50% of the pharmacists in the survey blamed time pressure, at least in part, for any deficiencies in prescription counseling. When 10 patients are waiting (impatiently) in line, a pharmacist may secretly hope none of them will accept counseling -- and may feel compelled to rush through counseling with any who do.

"There's such a high demand for drugs," Chen says, "and not always enough staff."

Pharmacists are generally paid simply on the basis of how many prescriptions they fill, so they get paid the same regardless of whether they counsel patients about their prescriptions.

And patients themselves are often most concerned about whether the medication is covered

by their insurance, says Kathy Besinque, an associate professor at the USC School of Pharmacy who also works part time at Patton's Pharmacy in Santa Monica. "If it's not, sometimes they just won't get it at all."

### Time to talk

As pressed as they may be for time, pharmacists generally have more of it to spend with patients than physicians do.

"These days physicians have to see three patients an hour," says Dr. Paul Gregerson, chief medical officer for the JWCH Institute in Los Angeles, a clinic that serves uninsured homeless people. "It relieves so much stress for them to know pharmacists are there to talk with patients, to educate and explain."

If and when pharmacists don't fill this role well, it may be because their customers don't give them a chance. Still, some pharmacists are bound to be more skilled than others.

"You should choose your pharmacist as carefully as you choose your physician," says Anne Burns, vice president for professional affairs for the American Pharmacists Assn.

That means checking out someone's training, experience and ability to communicate, says Ken Thai, owner of El Monte Pharmacy. "Ask, 'Hey, how did you get here? What do you know?' . . . Find someone you'd like to trust your life to."

Physicians wholeheartedly agree about the importance of the pharmacist's role. "Pharmacists know more about medications than anybody else in the healthcare system," Gregerson says. "That's what they went to school for. . . . They're like walking encyclopedias."

At the institute where Gregerson works, physicians and pharmacists collaborate closely on patient care. So he has seen firsthand what pharmacists can do and has found that their unique skills can save time, money, even lives. But, he believes, "pharmacists are totally under-utilized by society in general."

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# Nevada State Board of Pharmacy

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DATE: May 7, 2002  
TO: Board of Pharmacy Members  
FROM: Keith W. Macdonald *K. Macdonald*  
SUBJECT: Patient Counseling – Duty to Warn

The attached Supreme Court proceedings were distributed to all district and regional pharmacy managers. The cover memo is also enclosed.

It is presented to encourage the use of patient counseling to enhance public health, prevent medication errors and problems, and support the position of the Board as it relates to counseling.

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# Nevada State Board of Pharmacy

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DATE: May 7, 2002  
TO: Regional and District Pharmacy Managers  
FROM: Keith W. Macdonald *K. Macdonald*  
SUBJECT: Patient Counseling – Duty to Warn  
Supreme Court Ruling

The Nevada Board of Pharmacy has continually stressed the value of patient counseling.

Attached are the proceedings regarding a pharmacy duty to warn about a known drug contraindication. The Supreme Court considers the factors involved with counseling. It acknowledges the duty to warn is minimal, can prevent patient injury, is not practicing medicine or interrupting the doctor/patient relationship.

In the daily work place, haste to accommodate prescription dispensing, computer warnings are overridden and pharmacist/consumer interface is minimized. The cognitive values a pharmacist can provide to consumers of medicine needs to be emphasized.

Recently a spate of consumer complaints, as well as experiences of board office personnel, their spouses and/or friends suggest patient counseling is intermittent. Your help to encourage this valuable aspect of patient care is solicited.

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Docket No. 90482–Agenda 20–September 2001.  
HEIDI HAPPEL *et al.*, Appellees, v. WAL-MART STORES,  
INC., d/b/a Wal-Mart Pharmacy, Appellant.

JUSTICE McMORROW delivered the opinion of the court:

The central issue in this appeal is whether a pharmacy has a duty to warn about a known drug contraindication<sup>1</sup> where the pharmacy is aware of a customer's drug allergies and knows that the medication prescribed by the customer's physician is contraindicated for a person with those allergies. Plaintiff Heidi Happel, who is allergic to aspirin, ibuprofen, and acetaminophen, experienced a severe reaction after taking Toradol, a pain reliever prescribed by her physician, Dr. Zbigniew T. Lorenc. Toradol should not be taken by persons who are allergic to aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs). Heidi and her husband, plaintiff Kent Happel, subsequently brought a negligence action against Dr. Lorenc and Wal-Mart Stores, Inc., whose pharmacy in McHenry, Illinois, filled the prescription. Plaintiffs settled with Dr. Lorenc, and the trial court granted Wal-Mart's motion for summary judgment. The appellate court reversed (316 Ill. App. 3d 621), and we granted Wal-Mart's petition for leave to appeal. 177 Ill. 2d R. 315. For the reasons set forth below, we affirm the judgment of the appellate court.

#### BACKGROUND

On August 4, 1993, Heidi called Dr. Lorenc's office complaining of severe menstrual cramps. She sought a more effective pain reliever, and Dr. Lorenc prescribed Toradol. His office telephoned the prescription to the Wal-Mart pharmacy in McHenry, Illinois. Dr. Lorenc had been treating Heidi since December 1992, and he knew of her drug allergies. However, he stated in his deposition that on August 4, 1993, he did not know

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<sup>1</sup>The term "contraindication" is defined as "an indication, symptom, or condition that makes inadvisable a particular treatment or procedure." Webster's Third New International Dictionary 495 (1993).

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SUPREME COURT  
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that Toradol was contraindicated for patients with allergies to aspirin. If he had known this, he would not have prescribed Toradol for Heidi.

Prior to August 4, 1993, Heidi had been to the Wal-Mart pharmacy in McHenry about six times to have other prescriptions filled. Each time she went, pharmacy workers asked her if she had any drug allergies, and each time she told them she was allergic to aspirin, acetaminophen, and ibuprofen. Wal-Mart pharmacy manager Steven Odes testified in his deposition that in August 1993, it was the pharmacy's policy and procedure to ask customers about their known allergies prior to dispensing medication. The purpose of this practice, Odes said, was to alert the pharmacist to any drug interactions or allergies. Both Odes and Florence Bowser, another of defendant's pharmacists, testified that Heidi's allergy information was in the pharmacy's computer system and available to pharmacists on August 4, 1993, when Heidi's Toradol prescription was filled.

Bowser testified in her deposition that she was working at the Wal-Mart pharmacy on August 4, 1993, but she believed that Odes was also on duty that day. Bowser took the call from Dr. Lorenc's office and wrote down the Toradol prescription, but she did not remember actually filling the prescription. She said she had "no memory of the entire incident." Odes stated that he did not work at the pharmacy on August 4, 1993, and that Bowser was the only pharmacist on duty and therefore she filled the prescription. Odes also stated that Bowser would have had available to her the information that Toradol should not be given to patients with allergies to aspirin or other NSAIDs. According to Odes, Bowser "would know if there was a contraindication." Bowser indicated that she was aware that Toradol was contraindicated for persons who were sensitive to aspirin and ibuprofen.

If the Toradol information was in the pharmacy's computer, a "drug interaction" warning would have flashed across the screen, halting the prescription process for customers such as Heidi for whom Toradol was contraindicated. At that point, the pharmacist was to call the physician and notify him of the contraindication. Bowser did not remember calling Dr. Lorenc about Heidi's prescription, nor did she remember seeing any documentation indicating that she made such a call.

If, after being notified of a contraindication, a physician wanted the prescription filled anyway, the pharmacist would have to override the computer system by entering a special code. Odes testified that in order for Heidi's Toradol prescription to have been filled on August 4, 1993, Bowser would have had to override the system. He agreed that in such circumstances, to override the computer and fill the prescription without first contacting the physician would be a deviation from the standard of care applicable to pharmacists. Bowser testified that a pharmacist is required to know a customer's drug allergies and contraindications.

Once Heidi learned on August 4, 1993, that the prescription had been called in to the Wal-Mart pharmacy, she telephoned her husband, Kent, at work, and asked him to pick it up. Prior to this date, neither she nor Kent had ever heard of Toradol, which is an NSAID, as is aspirin. Kent went to the pharmacy to pick up the prescription, but before it was filled, a pharmacy worker asked him about Heidi's drug allergies. Kent informed the worker that Heidi was allergic to aspirin, ibuprofen, and acetaminophen.

There were directions on the bottle that Heidi received from the pharmacy, but there was no warning about contraindications. Heidi took the first dose of Toradol at about 4 p.m. on August 4, and within 40 minutes she began to experience respiratory problems including a tightness in her chest. She began a breathing treatment with a nebulizer, and called the pharmacy to ask if she could be having a reaction to Toradol. Her call was disconnected. She called again, and was told that there should be no drug reaction problem. Heidi then called a friend who was a pharmacist and was aware of her allergies. He told her to begin a nebulizer treatment if she had not already done so, and to go to the emergency room if her condition worsened. She went to the emergency room, and was found to be experiencing anaphylactic shock.<sup>2</sup> Heidi testified in her deposition that, as a result of taking

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<sup>2</sup>"Anaphylactic" is derived from the term "anaphylaxis," which is defined as "hypersensitivity (as to foreign proteins or drugs) \*\*\* manifested in man in acute serum sickness and in severe or fatal reactions to second or later administrations of certain drugs." Webster's Third New International Dictionary 78 (1993). In her deposition, Florence Bowser

Toradol, she subsequently experienced more frequent asthma attacks, as well as seizures and a worsening of her multiple sclerosis.

On September 30, 1994, plaintiffs filed a negligence action against Dr. Lorenc and Wal-Mart. On March 8, 1999, Wal-Mart filed a motion for summary judgment, and on March 15, 1999, plaintiffs settled with Dr. Lorenc and dismissed him from their complaint. Plaintiffs then moved to amend their complaint to add punitive damages claims. The trial court denied this request as well as Wal-Mart's motion for summary judgment. Plaintiffs filed an amended motion seeking to add punitive damages claims to their complaint.

Defendant Wal-Mart filed a motion to reconsider the denial of summary judgment, arguing that there was no legal duty for it to warn, and it did not voluntarily assume such a duty. On September 17, 1999, the trial court granted summary judgment in favor of defendant and denied plaintiffs' motion to amend their complaint. On appeal, the appellate court reversed the granting of summary judgment, concluding that defendant Wal-Mart owed plaintiffs a duty to warn. 316 Ill. App. 3d 621. However, the court made it clear that this duty was a narrow one:

"[U]nder the circumstances here, where defendant knew of Heidi's allergies, where defendant knew that Toradol was contraindicated for a person with Heidi's allergies, and where defendant knew that injury or death was substantially certain to result, defendant had an affirmative duty to disclose, either to Dr. Lorenc or to Heidi, the information that Heidi should not take Toradol." 316 Ill. App. 3d at 629.

The appellate court also affirmed the trial court's denial of plaintiffs' motion to amend their complaint.

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defined "anaphylactic shock" as follows: "It means the internal organs can swell, breathing passages can swell and the person can die."

## ANALYSIS

After granting Wal-Mart's petition for leave to appeal (177 Ill. 2d R. 315), we granted leave to the National Association of Chain Drug Stores to file an *amicus curiae* brief supporting defendant's arguments. We also granted leave for the National Association of Boards of Pharmacy (NABP) to file an *amicus curiae* brief supporting plaintiffs' arguments. Thereafter, Wal-Mart filed a motion before this court seeking to strike the NABP's brief for including materials outside the record. See *Zurich Insurance Co. v. Raymark Industries, Inc.*, 118 Ill. 2d 23 (1987); *Jenkins v. Wu*, 102 Ill. 2d 468 (1984). We ordered the motion taken with the case. We note that Wal-Mart had by motion objected to the same materials before the appellate court. That court denied the motion. Having reviewed the NABP's brief, we find, similar to the appellate court, that the materials provided by the NABP are relevant to standards of practice and care, and that such matters were raised in pleadings and depositions in this case. We therefore deny Wal-Mart's motion to strike the NABP's brief.

This matter is before this court on Wal-Mart's motion for summary judgment. In cases involving motions for summary judgment, we conduct a *de novo* review of the evidence in the record. *Espinoza v. Elgin, Joliet & Eastern Ry. Co.*, 165 Ill. 2d 107, 113 (1995). The purpose of a summary judgment proceeding is not to try an issue of fact, but to determine whether any genuine issue of material fact exists. *Frye v. Medicare-Glaser Corp.*, 153 Ill. 2d 26, 31 (1992); *Housh v. Swanson*, 203 Ill. App. 3d 377, 381 (1990). It is "a drastic means of disposing of litigation" (*Espinoza*, 165 Ill. 2d at 113) and therefore should be granted only when "the pleadings, depositions, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law" (735 ILCS 5/2-1005(c) (West 2000)). For purposes of summary judgment, we construe the facts strictly against the moving party and in the light most favorable to the nonmoving party. *Espinoza*, 165 Ill. 2d at 113; *Frye*, 153 Ill. 2d at 31.

As noted, the central issue before us concerns the existence of a duty, *i.e.*, whether defendant and plaintiffs stood in such a relationship to each other that the law imposed upon defendant an

obligation of reasonable conduct for the benefit of plaintiffs. *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507, 525 (1987); *Ward v. K mart Corp.*, 136 Ill. 2d 132, 140 (1990). " " "A duty to warn exists where there is unequal knowledge, actual or constructive [of a dangerous condition], and the defendant[,] possessed of such knowledge, knows or should know that harm might or could occur if no warning is given." " " [Citation.] *Schellenberg v. Winnetka Park District*, 231 Ill. App. 3d 46, 52 (1992), quoting *Pitler v. Michael Reese Hospital*, 92 Ill. App. 3d 739, 745 (1980), quoting *Kirby v. General Paving Co.*, 86 Ill. App. 2d 453, 457 (1967). "Whether a duty exists in a particular case is a question of law to be determined by the court." *Ward*, 136 Ill. 2d at 140; *Kirk*, 117 Ill. 2d at 525.

In determining whether a duty exists, courts look to certain relevant factors. These include: (1) the reasonable foreseeability that the defendant's conduct may injure another, (2) the likelihood of an injury occurring, (3) the magnitude of the burden of guarding against such injury, and (4) the consequences of placing that burden on the defendant. *Ward*, 136 Ill. 2d at 140-41; *Kirk*, 117 Ill. 2d at 525-26; *Colonial Inn Motor Lodge, Inc. v. Gay*, 288 Ill. App. 3d 32, 40 (1997).

It is undisputed that, at the time Heidi's prescription was filled on August 4, 1993, Wal-Mart was aware not only of Heidi's drug allergies, but also that the drug prescribed by Dr. Lorenc, Toradol, was contraindicated for persons such as Heidi who are allergic to aspirin. Given this superior knowledge on the part of Wal-Mart, and particularly given the nature of the knowledge, i.e., that Toradol was *contraindicated*, it was reasonably foreseeable that a failure to convey this knowledge might result in injury to Heidi. Both the likelihood and the reasonable foreseeability of injury here were great. These factors thus favor the imposition of a duty on Wal-Mart.

The burden on defendant of imposing this duty is minimal. All that is required is that the pharmacist telephone the physician and inform him or her of the contraindication. Alternatively, the pharmacist could provide the same information to the patient. Since this burden of warning about a contraindication is extremely small, this factor also favors the imposition of a duty here.

Next, we consider the consequences of imposing a duty to warn on defendant. As is discussed more fully below, defendant is not being asked to learn the customer's condition, nor is defendant being required to render a medical judgment or interject itself into the doctor-patient relationship. Instead, Wal-Mart need only pass along to the customer or the physician the information it already possesses about the contraindication for this specific customer. Such a practice apparently was already being followed at the Wal-Mart pharmacy in McHenry. Bowser testified in her deposition that prior to August 1993 she had had occasion "once, twice a month" to notify a physician about a patient's drug allergies. In these circumstances, the recognition of a duty to warn would simply require Wal-Mart to continue with a practice it was already engaged in.

Wal-Mart contends that imposing a duty to warn here would have a "chilling effect" on pharmacies and their customers. According to Wal-Mart, because the duty to warn is premised on the pharmacy's knowledge of a customer's allergies, the imposition of such a duty may discourage pharmacies from gathering information about customers' allergies in the first instance. In order to avoid this duty, pharmacies will no longer request allergy information or record it in their computers. Thus the pharmacy's customers will be deprived of potentially beneficial warnings. Therefore, Wal-Mart contends, no duty should be recognized. We disagree.

The consequence of accepting Wal-Mart's "chilling effect" argument would be to sanction the status quo, where pharmacies solicit allergy information from their customers but are under no obligation to follow through with a warning, even where the pharmacy knows that the drug being prescribed is contraindicated for the individual customer. The difficulty with this approach is that the status quo is unacceptable. By asking customers about their drug allergies, the pharmacy is engendering reliance in the customer that the pharmacy will take steps to ensure that the customer does not receive a drug to which the customer is allergic. There can be no other reason for a pharmacy's seeking this information regarding drug allergies. Where the pharmacy fails to warn the customer, then the customer is placed at risk of serious injury or death.

We do not disapprove of pharmacies' collecting allergy information and recording it in their computers. However, if a pharmacy chooses to engage in such a practice, it must also warn of known contraindications. The alternative, as noted, would place the customer at serious risk. We therefore conclude that any negative consequences of recognizing a duty to warn here are far outweighed by the substantial reasons favoring such a duty. Accordingly, this factor also supports the imposition of a duty on Wal-Mart.

We think that, given the circumstances in this case, Wal-Mart had a duty to warn and that this duty is encompassed within the pharmacist's duty of ordinary care. See *Eldridge v. Eli Lilly & Co.*, 138 Ill. App. 3d 124, 126 (1985) ("A pharmacist owes a duty of ordinary care in practicing his profession, but such care requires the highest degree of prudence, thoughtfulness and diligence, and it is proportioned to the danger involved"). As noted, Wal-Mart was aware not only of Heidi's drug allergies, but also that Toradol was contraindicated for persons with such allergies. A contraindication is a serious limitation on a drug's use, necessarily implying grave consequences if it is ignored. As one court has noted, a contraindication refers to "a circumstance under which the drug must never be given." *Hand v. Krakowski*, 89 A.D.2d 650, 651, 453 N.Y.S.2d 121, 123 (1982), cited with approval in *McKee v. American Home Products Corp.*, 113 Wash. 2d 701, 715, 782 P.2d 1045, 1053 (1989). Taking into account the potentially severe consequences of a failure to warn in this case, we conclude that imposing on Wal-Mart a duty to warn is clearly proportionate to "the danger involved." *Eldridge*, 138 Ill. App. 3d at 126.

Notwithstanding the foregoing, Wal-Mart argues that the appellate court below erred in finding that Wal-Mart had a duty to warn Heidi or Dr. Lorenc about the Toradol contraindication. Wal-Mart contends that because Illinois has adopted the learned intermediary doctrine, under which the prescribing physician has the primary responsibility to warn of drug interactions and side-effects, pharmacies in Illinois have no such duty. According to Wal-Mart, "[t]he learned intermediary doctrine exempts pharmacists and pharmacies from giving warnings to patients." Accordingly, Wal-Mart contends that, absent any duty to warn on Wal-Mart's part, the trial court was correct in granting summary



judgment in defendant's favor, and the appellate court's reversal of this judgment was in error. We disagree.

In support of its argument, Wal-Mart relies upon several Illinois cases, including *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507 (1987), wherein this court adopted the learned intermediary doctrine. In *Kirk*, the plaintiff was injured while riding as a passenger in a car driven by Daniel McCarthy, who had been a psychiatric patient at the defendant hospital. Certain prescription drugs were given to McCarthy on the day he was discharged from the hospital. On that same day, McCarthy consumed an alcoholic beverage. Later in the day, the car he was driving hit a tree, injuring the plaintiff. In his complaint, which named as defendants the hospital, the prescribing physicians, the manufacturers of the prescription drugs, and McCarthy, the plaintiff alleged, *inter alia*, that the hospital negligently failed to adequately warn McCarthy that the prescribed drugs would diminish his physical and mental abilities. The trial court dismissed the counts against most of the defendants, but the appellate court reversed and remanded the dismissed counts for trial.

In reversing the appellate court and affirming the trial court's decision, this court relied in part upon the learned intermediary doctrine. Under this rule, "manufacturers of prescription drugs have a duty to warn prescribing physicians of the drugs' known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients." *Kirk*, 117 Ill. 2d at 517. The underlying rationale of the learned intermediary doctrine is that, with regard to prescription drugs, which are likely to be complex medicines, it is the prescribing physician who knows both the propensities of the drug and the susceptibilities of his patient, and who therefore is in the best position to prescribe a particular drug for the patient. Accordingly, while drug manufacturers must warn the ultimate purchasers about the dangers inherent in *patent drugs sold over the counter*, the manufacturer need not warn the individual consumer about the dangers of *prescription drugs*. In selling these drugs, the manufacturer is required to warn only the prescribing physician, who then acts as a " "learned intermediary" " between the manufacturer and the consumer. *Kirk*, 117 Ill. 2d at 518, quoting *Stone v. Smith, Kline & French Laboratories*, 731 F.2d 1575,

1580 (11th Cir. 1984), quoting *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974).

Based on this doctrine, the court in *Kirk* held that the defendant drug manufacturers had no duty to warn patients directly. The court came to the same conclusion with regard to the defendant hospital:

"The extent of warnings to patients concerning prescription drugs, as we have previously noted, is within the discretion of the physician. As such, the alleged negligent acts specified in the complaint are matters within the duty of care owed by the treating physician, rather than the hospital." *Kirk*, 117 Ill. 2d at 524.

While the hospital might appear to have been acting in the role of a pharmacy, the court in *Kirk* did not directly address the question of whether the learned intermediary doctrine applied to pharmacies.<sup>3</sup> However, in the following year that question was addressed by our appellate court. In *Leesley v. West*, 165 Ill. App. 3d 135 (1988), a decision also relied upon by Wal-Mart, the second district appellate court applied the learned intermediary doctrine to pharmacists, and held that the defendant pharmacy had no duty to pass on to a customer relevant warnings given to it by the manufacturer of a prescription drug. The plaintiff in *Leesley* sued for damages resulting from severe gastrointestinal bleeding caused by the prescription drug Feldene. In her complaint, the plaintiff alleged, *inter alia*, that both the drug manufacturer and the pharmacy that filled the prescription failed to warn her directly about the potential hazards of the drug, including gastrointestinal bleeding, which is a known but infrequent side effect of Feldene.

The court in *Leesley* held that, based in part on the learned intermediary doctrine, neither the manufacturer nor the pharmacy had a duty to warn the customer directly of the potential side effects of Feldene. With regard to the pharmacy, the court

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<sup>3</sup>The court in *Kirk* did state in *dictum* that "negligence claims against pharmacists for failure to warn concerning overconsumption of drugs have been dismissed primarily because the manufacturers' warnings about prescription drugs are to be given to the physicians, who then had the duty to warn the patients." *Kirk*, 117 Ill. 2d at 526.

explained that the foreseeability of injury to an individual consumer "varies greatly depending on the medical history and condition of the individual-facts which we cannot reasonably expect the pharmacist to know." *Leesley*, 165 Ill. App. 3d at 142. The court in *Leesley* also noted that it would be "very burdensome" to require the pharmacy to convey to its customers the warnings it received from the manufacturer. Such a requirement might very well mean that pharmacists "must bear the additional costs of reproducing the material they receive." *Leesley*, 165 Ill. App. 3d at 142.

Other cases relied upon by Wal-Mart include *Eldridge v. Eli Lilly & Co.*, 138 Ill. App. 3d 124 (1985), and *Fakhouri v. Taylor*, 248 Ill. App. 3d 328 (1993), both of which address the question of whether a pharmacist has a duty to warn that drugs are being prescribed in excessive quantities. In each case, the court pointed to the learned intermediary doctrine in concluding that no such duty exists.

Relying on the foregoing and similar cases, Wal-Mart contends that the learned intermediary doctrine precludes the imposition of a duty to warn here. We disagree. Given the particular facts in the instant case, we conclude that this case is outside the purview of the learned intermediary doctrine.

As noted, the rationale underlying the learned intermediary doctrine is that because the prescribing physician has knowledge of the drugs he is prescribing and, more importantly, knowledge of his patient's medical history, it is the physician who is in the best position to prescribe drugs and monitor their use. Thus manufacturers of these drugs should not be required to warn individual patients of the dangers inherent in their use. That is the proper province of the prescribing physician, not the drug manufacturer, who has a duty only to warn the physician.

It is this rationale which underlies the reasons cited by the courts in *Leesley*, *Eldridge* and *Fakhouri* in explaining why pharmacists should not have a duty to warn a patient or physician of the adverse side effects of prescription drugs. Imposing such a duty, the court in *Eldridge* noted, "would require the pharmacist to learn the customer's condition and monitor his drug usage. To accomplish this, the pharmacist would have to interject himself into

the doctor-patient relationship and practice medicine without a license." *Eldridge*, 138 Ill. App. 3d at 127. Similarly, the court in *Fakhouri* asserted that "[d]etermining which medication is to be utilized in any given case requires an individualized medical judgment, which, in our opinion, only the patient's physician can provide." *Fakhouri*, 248 Ill. App. 3d at 332. The court noted that it is the physician who presumably knows the patient's current condition as well as his complete medical history. Therefore, the court in *Fakhouri* explained, "[t]o impose a duty to warn on the pharmacist would be to place the pharmacist in the middle of the doctor-patient relationship, *without* the physician's knowledge of the patient." (Emphasis in original.) *Fakhouri*, 248 Ill. App. 3d at 332-33. Along these same lines, the court in *Leesley* noted that a pharmacist cannot reasonably be expected to know the medical history and condition of the individual consumer, and therefore should not have a duty to warn individual consumers.

These reasons for not imposing a duty to warn on pharmacists do not apply in the instant case. Here, Wal-Mart was aware not only of Heidi's drug allergies, but also that Toradol was contraindicated for persons such as Heidi with allergies to aspirin. Imposing a duty to warn of this contraindication would not require the pharmacist to "learn the customer's condition and monitor his drug usage." *Eldridge*, 138 Ill. App. 3d at 127. On the contrary, Wal-Mart already had the knowledge it needed in order to give an effective warning, and this warning required Wal-Mart only to notify Dr. Lorenc or Heidi of the Toradol contraindication, not to monitor Heidi's drug usage.<sup>4</sup> Further, imposing a duty to warn here would not have intruded Wal-Mart into the doctor-patient relationship, forcing it to "practice medicine without a license." *Eldridge*, 138 Ill. App. 3d at 127. We agree with the appellate court below that "[t]his is not a case in which the plaintiff is asking the pharmacist to exercise any modicum of medical judgment or to

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<sup>4</sup>We note that the Pharmacy Practice Act of 1987 (225 ILCS 85/1 *et seq.* (West 2000)) defines "Pharmaceutical care" as including "the act of monitoring drug use." 225 ILCS 85/3(t) (West 2000). The narrow duty we impose here would not require the pharmacist to conduct such monitoring.

interject himself into the doctor-patient relationship." 316 Ill. App. 3d at 627-28.

The situation here differs from that in *Fakhouri* and *Eldridge*, where imposing the duty that the plaintiff sought would have required the pharmacist to warn that drugs were being prescribed in excessive quantities. As the court in *Eldridge* aptly noted, "[a] prescription which is excessive for one patient may be entirely reasonable for the treatment of another." *Eldridge*, 138 Ill. App. 3d at 127. Hence, imposing upon a pharmacist a duty to warn in such a situation might arguably require him to make a medical judgment. Here, the pharmacist was faced not with a prescription for a quantity in excess of normal use, but rather with a simple contraindication, which, as noted, means that the drug should not be given. See *Hand v. Krakowski*, 89 A.D.2d 650, 651, 453 N.Y.S.2d 121, 123 (1982); Webster's Third New International Dictionary 495 (1993). It requires no medical judgment simply to notify a physician or a patient of such a contraindication.

Contrary to Wal-Mart's contentions, the scope of the protection provided to pharmacists by the learned intermediary doctrine is limited, particularly in situations such as the instant case where a pharmacy has knowledge that a prescribed medication is contraindicated for a specific customer. With the exception of the appellate decision below in the case at bar, we have found no Illinois decisions addressing the question of a pharmacist's duty to warn in these circumstances. However, courts in other jurisdictions have addressed either this or similar issues. We find the decision in *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455 (Tex. Ct. App. 2000), particularly instructive with regard to the limitations of the learned intermediary doctrine in situations similar to the case at bar.

The plaintiffs in *Morgan* sued Wal-Mart Stores, Inc., alleging that their son's death in August 1993 resulted from an adverse reaction to Desipramine, a prescription drug sold by a Wal-Mart pharmacist. The plaintiffs alleged that Wal-Mart was negligent in failing to properly warn of the hazards and harms associated with the use of Desipramine. The jury agreed, finding that Wal-Mart's failure to warn was negligent, and that this failure was a proximate cause of the son's death. On appeal, Wal-Mart argued, as it does here, that its pharmacists had no duty to warn of the potential

dangers of Desipramine because that duty rested with the prescribing physician.

The appellate court in *Morgan* reversed the trial court, concluding that pharmacists have no generalized duty to warn of potential adverse reactions to prescription drugs. However, in reaching this conclusion, the court made clear the limitations in its holding. It noted specifically that the plaintiffs had not alleged that Wal-Mart possessed any special knowledge of their son's medical history that would have imposed upon Wal-Mart a duty to warn. In addition, the plaintiffs did not contend "that Wal-Mart was or should have been aware of any contraindications." *Morgan*, 30 S.W.3d at 467. The court in *Morgan* pointed to decisions in other jurisdictions where a duty was imposed on pharmacists "beyond accurately filing [*sic*] prescriptions \*\*\* based on the presence of additional factors, such as *known contraindications*, that would alert a reasonably prudent pharmacist to a potential problem." (Emphasis added.) *Morgan*, 30 S.W.3d at 466.

The court acknowledged that Wal-Mart might have been liable if there had been "neglect in the face of information on which a reasonably prudent pharmacist would have acted." *Morgan*, 30 S.W.3d at 467. In the absence of such information, however, there was no liability. Hence, the court's carefully worded holding in *Morgan*:

"[I]n light of the learned intermediary doctrine, which we find applicable to the relationship among physician, patient, and pharmacist, we hold that pharmacists have no generalized duty to warn patients of potential adverse reactions to prescription drugs *absent some special circumstances not present here*." (Emphasis added.) *Morgan*, 30 S.W.3d at 469.

In the instant case, by contrast, such "special circumstances" were present. It is undisputed that Wal-Mart had "special knowledge" of Heidi's medical history, *i.e.*, her drug allergies. In addition, Wal-Mart knew that Toradol was contraindicated for persons such as Heidi with allergies to aspirin and other NSAIDs. In such limited circumstances, a narrow duty to warn clearly exists. See *McKee v. American Home Products Corp.*, 113 Wash. 2d 701, 715, 782 P.2d 1045, 1053 (1989) (agreeing that "pharmacists

should have a duty to be alert for patent errors in a prescription, [including] \*\*\* known contraindications \*\*\* and to take corrective measures" (emphasis omitted)).

For the reasons set forth above, we hold that a narrow duty to warn exists where, as in the instant case, a pharmacy has patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient. In such instances, a pharmacy has a duty to warn either the prescribing physician or the patient of the potential danger.

Because of our disposition on the duty of the pharmacy, we need not address Wal-Mart's argument that it engaged in no voluntary undertaking to warn, and therefore did not remove itself from the protection of the learned intermediary doctrine. See *Kasin v. Osco Drug, Inc.*, 312 Ill. App. 3d 823, 827 (2000) (concluding that under *Frye v. Medicare-Glaser Corp.*, 153 Ill. 2d 26 (1992), the learned intermediary doctrine no longer applies once a pharmacist voluntarily undertakes to warn a consumer of a drug's dangerous propensities). The duty we impose here is beyond the scope of the learned intermediary doctrine. Thus it is irrelevant whether Wal-Mart removed itself from the protection of this rule. The learned intermediary doctrine is simply not implicated by the circumstances in this case.

#### CONCLUSION

Because we have concluded that Wal-Mart owed a narrow duty to warn in this case, there remains a genuine issue of material fact as to whether Wal-Mart breached this duty, and if so, whether this breach proximately caused Heidi's injuries. Summary judgment therefore was improper. Accordingly, we affirm the judgment of the appellate court below, which reversed the trial court's granting of summary judgment and remanded the cause for further proceedings.

*Affirmed.*

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## BOARD MEETING

at the

Las Vegas Chamber of Commerce  
Turnberry Town Square  
6671 Las Vegas Boulevard, South  
Building D1, Suite 300  
Las Vegas

January 13<sup>th</sup> & 14<sup>th</sup>, 2010

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

### Board Members Present:

Keith Macdonald	Beth Foster	Kirk Wentworth
Donald Fey	Chad Luebke	Kam Gandhi
Mary Lau		

### Board Members Absent:

Mary Lau was not present on January 13<sup>th</sup>, 2010.

### Board Staff Present:

Larry Pinson	Jeri Walter	Carolyn Cramer	Nancy Savage
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## CONSENT AGENDA

1. Approval of December 2-3, 2009, Minutes
2. Applications for Out-of-State MDEG – Non Appearance:
  - A. Binson's Hospital Supplies, Inc. – Center Line, MI
  - B. Orbit Medical of Indiana, Inc. – Indianapolis, IN
  - C. National Seating & Mobility, Inc. – Sacramento, CA
  - D. North Coast Medical Supply – Carlsbad, CA
  - E. PharMerica – Smyrna, GA
  - F. Sanvita CBGM, LLC – Bedford, MA
  - G. Symbios Medical, LLC – Phoenix, AZ

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

- H. Costco Wholesale Corporation – Corona, CA

- I. Depot Drug – Salt Lake City, UT
- J. Griff's Compounding Center, Inc. – Scottsbluff, NE
- K. Express Scripts, Inc. – Phoenix, AZ
- L. Lee Silsby Compounding Pharmacy – Cleveland Heights, OH
- M. Precision Pharmacy – Bakersfield, CA
- N. Preferred Rx, LLC – Arlington, TX

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

- O. Aidapak Services, LLC – Vancouver, WA
- P. Bioform Medical, Inc. – Franksville, WI
- Q. Butler Schein Animal Health Supply – Columbus, OH
- R. Butler Schein Animal Health Supply – Salt Lake City, UT
- S. Butler Schein Animal Health Supply – Tualatin, OR
- T. Butler Schein Animal Health Supply – Visalia, CA
- U. Cardinal Health – Valencia, CA
- V. DeRoyal Industries, Inc. – New Tazewell, TN
- W. Fresenius Medical Care North America – Los Lunas, NM
- X. Glenwood-LLC – Englewood, NJ
- Y. Medicis Aesthetics, Inc. – Scottsdale, AZ
- Z. Medicis, The Dermatology Company – Scottsdale, AZ
- AA. Owens & Minor Healthcare Logistics – Louisville, KY
- BB. Physicians' Pharmaceutical Corporation – Oak Ridge, TN
- CC. Promotech – Totowa, NJ
- DD. Ucyclyd Pharma, Inc. – Scottsdale, AZ

Applications for Nevada MDEG – Non Appearance:

- EE. Hathaway Medical – Las Vegas
- FF. True Pharmacy – Las Vegas
- GG. Zee Medical Service Company – Las Vegas

Applications for Nevada Pharmacy – Non Appearance:

- HH. BHS Specialty Pharmacy – Las Vegas
- II. Horizon Surgical Center – Henderson
- JJ. Metro Drugs – Las Vegas
- KK. Nevada Drug Compounding Pharmacy East – Henderson
- LL. Nevada Drug Compounding Pharmacy West – Las Vegas
- MM. Remedy Rx – Las Vegas
- NN. Smoke Ranch Surgery Center – Las Vegas
- OO. True Pharmacy – Las Vegas

Discussion:

The consent agenda applications and supporting documents were reviewed. Larry Pinson asked the Board to pull Items M, EE and NN for discussion.

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 M, EE and NN.

Second: Kam Gandhi

Action: Passed Unanimously.

Motion: Chad Luebke found the minutes to be accurate and complete and moved for approval.

Second: Kirk Wentworth

Action: Passed Unanimously.

Discussion:

Item M, Precision Pharmacy, failed to check that they plan on shipping parenterals into Nevada which requires an appearance. Larry Pinson asked that the license be granted with the understanding that they must appear prior to expanding that license to include parenterals.

Board Action:

Motion: Chad Luebke moved to approve the application with the understanding that they will not ship parenterals into Nevada until they have appeared before the Board.

Second: Keith Macdonald

Action: Passed Unanimously

Item EE, Hathaway Medical, indicated on their application that they had been involved in a lawsuit however they gave no explanation. Hathaway Medical deals in bone growth stimulators.

Board Action:

Motion: Keith Macdonald moved to table this application until Board staff can obtain information regarding the lawsuit.

Second: Kam Gandhi

Action: Passed Unanimously

Item NN, Smoke Ranch Surgery Center, also indicated on their application that there was some sort of legal issue and they did not provide any explanation. Board staff was directed to change the application to require an explanation if they answer "yes" to any of the questions regarding lawsuits, arrests, administrative actions, etc.

Board Action:

Motion: Keith Macdonald moved to table this application until Board staff can obtain information regarding the legal issue.

Second: Beth Foster

Action: Passed Unanimously

REGULAR AGENDA

3. Disciplinary Actions:

- |    |                        |                |
|----|------------------------|----------------|
| A. | Warren C. Rolen, R.Ph  | (09-040-RPH-S) |
| B. | Mountain View Pharmacy | (09-040-PH-S)  |

This matter was continued to the April Board meeting.

- |    |                        |                |
|----|------------------------|----------------|
| C. | William C. Colton, PTT | (09-107-PTT-S) |
|----|------------------------|----------------|

Carolyn Cramer advised the Board that Mr. Colton was notified of the hearing at his last known address and he failed to appear.

Ms. Cramer explained that Mr. Colton diverted controlled substances from his employing pharmacy. In his written statement he admitted that he diverted approximately 300 hydrocodone/APAP 10/500 tablets and 20 Xanax tablets for his personal use for a total loss to his pharmacy of approximately \$175.37.

Board Action:

Motion: Chad Luebke moved to find Mr. Colton guilty of the alleged violations.

Second: Keith Macdonald

Action: Passed Unanimously

Motion: Chad Luebke moved to revoke Mr. Colton's pharmaceutical technician in training registration.

Second: Keith Macdonald

Action: Passed Unanimously

Carolyn Cramer explained that Ms. Wells was notified of the hearing at her last known address and she failed to appear.

Ms. Cramer explained that Ms. Wells diverted controlled substances from her employing pharmacy. In her written statement she admitted that she had been diverting hydrocodone/APAP 10/500 since March, 2008. Ms. Wells would take bottles of 100 and transfer the tablets to an empty Excedrin bottle. Ms. Wells estimated that she diverted approximately 235 bottles of 100 hydrocodone 10/500 at a loss to her pharmacy of approximately \$10,126.15.

Board Action:

Motion: Mary Lau moved to find Ms. Wells guilty of the alleged violations.

Second: Keith Macdonald

Action: Passed Unanimously

Motion: Mary Lau moved to revoke Ms. Wells' pharmaceutical technician registration.

Second: Beth Foster

Action: Passed Unanimously

4. Requests for Pharmaceutical Technician in Training License – Appearance:

A. Anzon Pablo

Anzon Pablo appeared and was sworn by President Fey prior to answering questions or offering testimony.

Carolyn Cramer explained that Mr. Pablo had answered yes to one of the questions on the application for pharmaceutical technician in training indicating that he had a gross misdemeanor criminal conviction in Clark County and was present to explain the circumstances.

Mr. Pablo advised that he was attending the Pima Institute and was enrolled in the pharmaceutical technician program. He indicated that he entered into an Alford Plea so he would not have to continue with the court case. He stated that he had attended a party and two girls claimed that he had assaulted them. When the case went to hearing, the girls that made the accusation advised the Judge that they wanted to drop the charges. Even though they requested the charges be dropped, the Judge sentenced Mr. Pablo to three years probation, required him to pay a \$500.00 fine, obtain counseling, have a substance abuse evaluation and perform 100 hours of

community service. Mr. Pablo has complied with all of the requirements of his probation and noted that the substance abuse evaluation showed a low propensity toward addiction.

Board Action:

Motion: Keith Macdonald moved to accept the application for pharmaceutical technician in training for Mr. Pablo.

Second: Chad Luebke

Action: Passed Unanimously

B. Genero Siciliano

Genero Siciliano appeared and was sworn by President Fey prior to answering questions or offering testimony.

Ms. Cramer explained that Mr. Siciliano also answered yes to a question on his application for pharmaceutical technician in training and was present to explain the circumstances.

Mr. Siciliano explained to the Board that he and his girlfriend had a heated argument earlier in the day of the incident and she left to stay with a friend. The friend heard about the argument, contacted the police and advised them that Mr. Siciliano had a shotgun. Later that evening the police arrived at Mr. Siciliano's home and asked him about the weapon. He indicated it was unloaded and in the house. The police officers asked him to leave his property and he refused, asking them if they had a warrant. The officers then advised him that he was obstructing justice and arrested him. Mr. Siciliano advised the Board that he understands that what he did was not the appropriate thing to do, however, that was what he was arrested for. Mr. Siciliano indicated that he had a court date on January 25<sup>th</sup>, 2010 and would have a judgment at that time.

Board Action:

Motion: Keith Macdonald moved to table the application for pharmaceutical technician in training until the April meeting, pending the outcome of January 25<sup>th</sup> hearing.

Second: Chad Luebke

Action: Passed Unanimously

5. Request for Pharmacist License – Examinee – Appearance:

David Katsules

David Katsules and Larry Espadero, PRN-PRN monitor, appeared and were sworn by President Fey prior to answering questions or offering testimony.

Mr. Katsules explained that the PRN-PRN program is the best thing he has ever done for himself. He has learned how to cope with issues he found insurmountable while he was under the influence of alcohol. Mr. Espadero affirmed that Mr. Katsules has been in the PRN-PRN program since January, 2006 and has been in compliance with his contract since Mr. Katsules came to him from Oregon. Mr. Katsules explained that he had a DUI in August, 2004 in Las Vegas. He reported this to the Oregon Board where they Ordered him into treatment and allowed him to be monitored by Mr. Espadero. Mr. Katsules explained that he is currently working in Arizona on an Indian reservation, however he would like to come home to Las Vegas and practice in Nevada. Mr. Katsules requested that he be allowed to take the NAPLEX exam for Nevada.

Board Action:

Motion: Chad Luebke moved to approve the request for Mr. Katsules to take the NAPLEX for Nevada.

Second: Beth Foster

Action: Passed Unanimously

6. Request for Pharmacist License – Reciprocal – Appearance:

Madonna Wilcox

Madonna Wilcox was notified that her application was going to expire if she did not appear at this meeting to request reciprocity. Ms. Wilcox did not appear.

Board Action:

Motion: Kam Gandhi moved to deny Ms. Wilcox's request for reciprocity.

Second: Beth Foster

Action: Passed Unanimously

7. Request for Reinstatement of Pharmacist License – Appearance:

Zachary W. Bergan

(07-083-RPH-N)

Zach Bergan appeared and was sworn by President Fey prior to answering questions or offering testimony.

NOTE: Kirk Wentworth recused from participation in this matter as he used to employ Mr. Bergan.

Mr. Bergan provided letters of recommendation, a resume of his pharmacy accomplishments and an employment history other than pharmacy. Mr. Bergan was very open with the Board regarding his dependence on controlled substances and what he has been doing since his license was revoked in March, 2008. He indicated that he has been in Connecticut for the last two years where he has family and a support group of friends. He indicated that he would like to have his license reinstated in Connecticut however he knew he would have to reinstate in Nevada first since Connecticut paralleled the Nevada action. The Board was interested in what kind of treatment he had been in, however the paperwork was not in his file for Carolyn Cramer to reference. After discussion it was determined to table Mr. Bergan's request until he could provide proof of treatment for at least a six month period.

Board Action:

Motion: Chad Luebke moved to table Mr. Bergan's request for reinstatement until he can provide the Board with proof that he had been in a treatment program for at least six months.

Second: Mary Lau

Action: Passed Unanimously

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

Altius Healthcare – Prescott, AZ

Kevin Nestruck appeared and was sworn by President Fey prior to answering questions or offering testimony.

Carolyn Cramer explained that Mr. Nestruck answered yes to one of the questions on the application for out of state pharmacy and is present to explain the circumstances.

Mr. Nestruck explained that he owned two or three stores in Arizona. During an inspection it was found that one of his stores failed to have a rubber spatula and a "C" stamp. The Arizona Board charged him personally as the owner with the violations rather than the responsible managing pharmacist in that particular store. Mr. Nestruck advised the Board that he is now the owner of eleven facilities and all of them are 797 compliant with no further violations found in any of his stores.

Board Action:

Motion: Keith Macdonald moved to approve the application for out of state pharmacy for Altius Healthcare.

Second: Mary Lau

Action: Passed Unanimously



9. Your Success Report:

Burke's Drug

Larry Pinson advised the Board that Katie Johnson, Herb Burke and Ted Mackie came to the Board office and met with him and Carolyn Cramer for their Your Success Rx Report. Mr. Pinson reminded the Board that originally they had no policies and procedures in their pharmacy including a standardized NDC check to ensure medication accuracy which was the primary reason for their discipline. Policies and procedures now exist. Ms. Johnson advised them that they needed to set cleanliness standards and they had the bathroom professionally cleaned and bought a vacuum cleaner. Mr. Pinson indicated that they felt the program was beneficial to their pharmacy practice and the monthly inspections showed a marked improvement overall, and recommended that probation be lifted.

Board Action:

Motion: Kirk Wentworth moved to take Burke's Drug off probation.

Second: Keith Macdonald

Action: Passed Unanimously

10. Presentation:

Preparing for Regulatory Inspectors & Inspecting for Safety  
Larry Pinson & Katie Johnson

Mr. Pinson advised the Board that he and Ms. Johnson put this program together and have presented it to a group at Scolari's and wanted the Board to see it since it will be the basis of this years law CE. The presentation was given and well received by the Board.

11. General Counsel Report:

Sanchez v. Wal-Mart

Ms. Cramer summarized the Sanchez v. Wal-Mart decision for the Board. She also advised them that we prevailed in the appeal for the McKesson contract.

12. Executive Secretary Report:

A. Financial Report

B. Investment Report

Larry Pinson gave the financial and investment reports to the Boards satisfaction.

C. Temporary Licenses

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

#### D. Staff Activities

- Katie Johnson and he presented the “Inspecting for Safety” program to a group of Scolari’s pharmacy staff and it was well received. Mr. Pinson advised that he and Ms. Johnson will make the presentation to them later in the meeting.
- Mr. Pinson noted that he gave a talk to a medical staff credentialing group last night.
- He advised that he will be making a presentation for the Nevada Osteopathic Medical Association (NOMA) at Lake Tahoe on January 22<sup>nd</sup>.
- Mr. Pinson and Carolyn Cramer will be setting up a meeting with Mo Denis in the upcoming weeks to discuss prescription drug abuse as mandated by the legislature.
- He will also do a presentation to Northern Nevada Dental Society on prescription drug abuse and current dental drug issues.

#### E. Reports to Board

- Mr. Pinson presented the AB128 Marketing Code of Conduct Annual Compliance Report for the Board’s review. He also indicated that he may do a program again for the manufacturers and wholesaler’s here on the west coast in April.
- Larry Pinson also reported that he has agreed to do Fax blasts for the Health Department when they have pertinent information to disseminate.
- NABP has reviewed the new owners of ICPT and it looks favorable that the program will continue with the previous owners’ standards.
- Mr. Pinson advised the Board that he received a call from Rich Polombo of Medco Health Solutions. Mr. Polombo stated that Medco would like to ship AIDS drugs and antibiotics by the palate to Haiti for the survivors of the devastating earthquake. Mr. Pinson advised the Board that he gave Mr. Polombo his approval to supply that humanitarian support to Haiti.

#### F. Activities Report

### 13. Discussion and Determination:

#### A. Refrigerator Log

Mr. Pinson reported that Ray Seidlinger has found a lot of discrepancies throughout all pharmacies he inspects where they are not documenting or checking their refrigerators on a regular basis to ensure proper temperature levels. He has found variances in temperature, precipitation in vials and virtually no procedures in place. Mr. Pinson asked the Board to consider regs to mandate a refrigerator log to ensure biologicals are protected for patient safety.

President Fey noted that non-industrial refrigerators cycle too often and it’s difficult to maintain consistent temperatures. Beth Foster agreed and noted that the VA has ordered pharmacy quality refrigerators for her facility. Keith Macdonald wanted to know what the Board is going to do to pharmacies that cannot keep the refrigerator at consistent temperatures. Mr. Pinson advised that the law already requires pharmacies to keep drugs safely stored and all Board staff is asking for is a log to show that temperatures are being checked regularly. Chad Luebke indicated that was a good

practice to ensure public safety. The Board agreed and instructed Carolyn Cramer to draft regs and bring them forward in Workshop format.

#### B. Scheduling of Propofol as a Controlled Substance

Larry Pinson reported that he took this issue to the Task Force meeting and they did not think scheduling Propofol was necessary. Mr. Pinson asked President Fey how it would affect the hospital setting. President Fey indicated that various other states are already treating Propofol like a controlled substance. He did not think scheduling Propofol was necessary. Beth Foster agreed and did not think it would be beneficial. It was noted that the hospitals are not particularly worried but perhaps it was more of an issue in surgery centers. The Board was advised that if they choose to schedule Propofol they should be prepared to hear from the manufacturers and anesthesiologists. Mr. Pinson advised the Board that Propofol is somewhat difficult to abuse because it is so rapidly acting that it generally takes someone other than the abuser to administer.

The Board directed staff to contact NABP, the DEA, law enforcement and the coroner to get their take on this issue and report back.

#### C. Scheduling of Lisdexamfetamine, Lacosamide and Tapentadol as Controlled Substances

Mr. Pinson received a request from Tracy Birch, the forensic lab manager for the Las Vegas Metro Police Department, asking the Board to schedule Lisdexamfetamine, Lacosamide and Tapentadol. Ms. Birch noted that the DEA has already scheduled Lisdexamfetamine and Tapentadol in Schedule II and Lacosamide in Schedule V and asked that we parallel the federal law.

#### Board Action:

Motion: Kam Gandhi moved to make the regulatory changes necessary to schedule Lisdexamfetamine, Lacosamide and Tapentadol to parallel federal law.

Second: Keith Macdonald

Action: Passed Unanimously

#### \*14. Discussion on Patient Counseling

At Mr. Macdonald's request a discussion was held including all of the Board inspectors and investigators on counseling. The core of the discussion was to develop an appreciation for Board staffs duty to enforce our statutes and regulations as well as understand the challenges working pharmacists face in meeting counseling standards.

Joe Kellogg and Khanh Pham appeared and offered their thoughts.

## WORKSHOP

### \*15. **Proposed Regulation Amendment Workshop**

**Amendment of Nevada Administrative Code 639.NEW Telepharmacy Regulation** This language sets the parameters for a pharmacist or dispensing practitioner to practice from a remote site.

Carolyn Cramer and Larry Pinson advised the Board that this issue evolved from Assemblyman Carpenter's bill in the last legislative session. The only pharmacist in Wells retired and no one took his place. Wells had a physician, however he had no interest in becoming a dispensing practitioner, leaving the community without access to pharmaceutical care. The concept of satellite pharmacy and telepharmacy was the result.

Lillian Shell, representing Nevada Health Centers appeared and provided suggestions to the language as presented. Ms. Shell described how a doctor goes from one location to another to serve the rural community. She noted that they would only dispense to their own patients – someone would not be able to come in with a written prescription to be filled.

Carolyn Cramer described Board staff's vision of this concept regarding training, the people that would be allowed to perform Telepharmacy, etc. Larry Pinson said he does not want to see a pharmaceutical technician in the rural settings without the supervision of a pharmacist. Ms. Shell indicated that it would be a hardship to have to wait for a technician to receive 500 hours of training because then they would have to have two people, a trained technician and the trainee, instead of one person manning the rural Telepharmacy location. Mr. Pinson reminded the Board that the PA's and APN's started out in the rurals and now are practically all practicing in urban settings in Nevada.

Various suggestions were made and Board staff was directed to bring the language back again for a second Workshop after some of the suggestions are incorporated.

### 15. Next Board Meeting:

March 3 & 4, 2010 – Reno, Nevada

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

Liz Macmenamin asked that the Board not limit monitoring and keeping a refrigerator log to pharmacist's duties – allowing other pharmacy staff to monitor refrigerator temperatures.