

BEFORE THE NEVADA STATE BOARD OF PHARMACY

|  |   |                           |
|--|---|---------------------------|
| NEVADA STATE BOARD OF PHARMACY,        | ) | CASE NO. 16-014-RPH-S     |
|  | ) |                           |
| Petitioner,                            | ) |                           |
| v.                                     | ) | NOTICE OF INTENDED ACTION |
|  | ) | AND ACCUSATION            |
| LISA HARRIS BAKER, R.PH.               | ) |                           |
| Certificate of Registration No. 14725, | ) |                           |
|  | ) |                           |
| Respondent.                            | / |                           |

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, 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 (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Lisa Harris Baker (Ms. Baker), Certificate of Registration 14725, was a pharmacist registered with the Board.

II.

On May 15, 2014, Board Staff sent Ms. Baker a letter informing her that she had not completed the required thirty (30) continuing education units (CEUs) for the November 1, 2011, to October 31, 2013, renewal period. The letter was sent based on the results of a random audit conducted by Board Staff which identified that Ms. Baker completed only twelve (12) units of the required thirty (30) CEUs.

III.

In the May 2014 letter, Board Staff directed Ms. Baker to complete a total of one-hundred and eight (108) CEUs for the biennium ending October 31, 2015, in lieu of formal discipline. That one-hundred and eight (108) CEUs consisted of:

- Eighteen (18) CEUs Ms. Baker failed to complete for the renewal period of November 1, 2011 to October 31, 2013; and
- Ninety (90) CEUs for the renewal period of November 1, 2013 through October 31, 2015.

The letter stated that Ms. Baker's CEUs would be audited for the renewal period of November 1, 2013, through October 31, 2015, to verify compliance with the Board Staff's instructions.

IV.

In November 2015, after Ms. Baker should have completed the one-hundred and eight (108) CEUs, she contacted a Board Staff by phone and stated that she did not complete the required CEUs for the November 1, 2013 to October 31, 2015 renewal period.

V.

Ms. Baker signed her pharmacist license renewal application in December 2015. By signing the application, she certified that she had completed all required CEU hours due for the November 1, 2013 to October 31, 2015 renewal period.

VI.

As stated in the May 2014 letter, Board Staff notified Ms. Baker in early 2016 that she is required to provide documentation of the CEUs she completed for the biennium ending October 31, 2015.

VII.

Ms. Baker did not respond to the Board Staff's CEU audit requests. The first notice was an email sent out January 22, 2016, with a deadline of February 10, 2016. The second notice was a letter mailed on February 12, 2016, with a deadline of March 8, 2016.

VIII.

Therefore, Board Staff's CEU audit findings are that Ms. Baker completed none of the required one-hundred and eight (108) CEUs for the biennial period November 1, 2013, to October 31, 2015.

**FIRST CAUSE OF ACTION**

IX.

By failing to complete the one-hundred and eight (108) CEUs ordered in the Board Staff's May 15, 2014 letter, Lisa Harris Baker violated Nevada Administrative Code (NAC)

639.330, which violations are grounds for action pursuant to Nevada Revised Statute (NRS) 639.210(4) and/or (12), NRS 639.2174, and NRS 639.255.

**SECOND CAUSE OF ACTION**

X.

By failing to respond to the Board Staff's request for documents relating to her CEUs, Lisa Harris Baker violated NAC 639.330 and/or NAC 639.945(m), which violations are grounds for action pursuant to NRS 639.210(4), (12), and/or (17), and NRS 639.255.

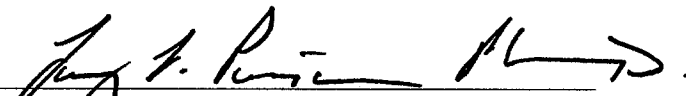
**THIRD CAUSE OF ACTION**

XI.

By signing her renewal application and certifying that she had completed the required CEUs for the biennial period of November 1, 2013, to October 31, 2015, when she completed no CEUs, Lisa Harris Baker violated NRS 639.281, which violations are grounds for action pursuant to NRS 639.210(4), (9), (10), and/or (12), and NRS 639.255.

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 22<sup>nd</sup> day of March, 2016.

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

**NOTICE TO RESPONDENTS**

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**

|  |   |                                    |
|--|---|------------------------------------|
| <b>NEVADA STATE BOARD OF PHARMACY,</b>       | ) | <b>CASE NO. 16-014-RPH-S</b>       |
|  | ) |                                    |
| <b>Petitioner,</b>                           | ) | <b>STATEMENT TO THE RESPONDENT</b> |
| <b>v.</b>                                    | ) | <b>NOTICE OF INTENDED ACTION</b>   |
|  | ) | <b>AND ACCUSATION</b>              |
| <b>LISA HARRIS BAKER, R.PH.</b>              | ) | <b>RIGHT TO HEARING</b>            |
| <b>Certificate of Registration No. 14725</b> | ) |                                    |
|  | ) |                                    |
| <b>Respondent.</b>                           | ) |                                    |

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TO THE RESPONDENT ABOVE-SAMED: 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.

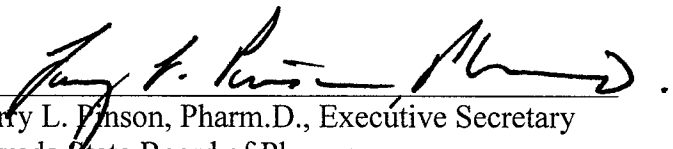
III.

The Board has reserved Wednesday, July 20, 2016, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., 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 22<sup>nd</sup> day of March, 2016.

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

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| <b>NEVADA STATE BOARD OF PHARMACY,</b>       | ) | <b>CASE NO. 16-014-RPH-S</b> |
|  | ) |                              |
| <b>Petitioner,</b>                           | ) |                              |
| <b>v.</b>                                    | ) |                              |
|  | ) | <b>ANSWER AND</b>            |
| <b>LISA HARRIS BAKER, R.PH.</b>              | ) | <b>NOTICE OF DEFENSE</b>     |
| <b>Certificate of Registration No. 14725</b> | ) |                              |
|  | ) |                              |
| <b>Respondent.</b>                           | / |                              |

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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 her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against her, 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, she 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 March, 2016.

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LISA HARRIS BAKER, R.PH.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

|  |   |                      |
|--|---|----------------------|
| NEVADA STATE BOARD OF PHARMACY,          | ) | CASE NO. 16-001-PH-S |
|  | ) |                      |
| Petitioner,                              | ) |                      |
| v.                                       | ) | AMENDED NOTICE OF    |
|  | ) | INTENDED ACTION AND  |
| WAL-MART PHARMACY #10-5269               | ) | ACCUSATION           |
| Certificate of Registration No. PH01985, | ) |                      |
|  | ) |                      |
| Respondents.                             | ) |                      |
|  | / |                      |

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Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, 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.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Wal-mart Pharmacy #10-5269 (Wal-mart), Certificate of Registration No. PH01985, was a pharmacy registered with the Board.

FACTUAL ALLEGATIONS

II.

While investigating a complaint filed in December 2015, a Board Investigator discovered that Wal-mart had dispensed a prescription for Hydromorphone 4 mg. (#120) to patient L.T. without an original prescription.

III.

The history underlying that dispensing error began on November 24, 2015, when patient L.T. went to a physician and received a prescription for Dilaudid (hydromorphone) 4 mg. tablets (#120).



IV.

L.T. tendered the prescription to Wal-mart that day.

V.

The Wal-mart pharmacist on duty scanned the prescription into Wal-mart's computer system and assigned it Prescription No. 2220825. The pharmacist also placed a bar-coded sticker unique to Prescription No. 2220825 on the front of the original hard copy.

VI.

Wal-mart's system then placed the prescription on an insurance hold.

VII.

The insurance hold was resolved on November 27, 2015, and Prescription No. 2220825 proceeded through Wal-mart's filling process. At 3:29 p.m., a pharmacist performed a "four point check" and Drug Utilization Review (DUR) on the prescription and approved it for filling.

VIII.

The store had insufficient stock to fill the prescription, and the prescription was placed back on hold in a "resolution" status.

IX.

The store informed L.T. that the store had insufficient stock and could not fill her prescription. L.T. returned to Wal-mart on November 27, 2015 at 6:17 p.m. to retrieve the hard copy.

X.

Wal-mart's records indicate that pharmacy technician in training (PTT), Ashley Day, gave the original hardcopy of the prescription back to L.T. upon her request.

XI.

Ms. Day did not record in Wal-mart's computer system that the patient picked up the prescription, nor did she cancel the prescription.

XII.

Patient L.T. took the prescription to a Walgreens pharmacy. Walgreens scanned the prescription on November 27, 2015 at 6:30 p.m., and assigned it prescription No. 1247867.

XIII.

Walgreens filled the prescription and dispensed the medication to L.T. later that day.

XIV.

Three days later, on November 30, 2015, Wal-mart received the hydromorphone it needed to fill Prescription No. 2220825.

XV.

Using the scanned image of the prescription in the computer system, the store proceeded with the filling process for Prescription No. 2220825. Part of this process required printing a second sticker to be attached to the back of the original prescription after completion of the “four point check”.

XVI.

At this point, the original prescription was no longer held at Wal-mart. Instead of flagging the prescription as having an “issue” due to the pharmacy’s inability to locate the original prescription, a pharmacy staff member—Wal-mart’s records do not indicate who—attached that second sticker to a photocopy of the original prescription.

XVII.

Prescription No. 2220825 was put on another hold after the patient’s insurance declined to pay for the medication.

XVIII.

On December 12, 2015, the insurance issue was resolved and Wal-mart again resumed the filling process for Prescription No. 2220825.

XIX.

The following morning, pharmacy technician Anne Marie Pangilinan filled the prescription.

XX.

A Wal-mart pharmacist performed the product verification and verified the prescription's accuracy using the *scanned* copy of the prescription in Wal-mart's system.

XXI.

Wal-mart then contacted L.T. to inform her that her prescription (No. 2220325) was ready to pick up.

XXII.

Pharmacist Thuy Mai counseled L.T. on the prescription and sold it to her on December 13, 2015.

RELEVANT LAW

XXIII.

NRS 453.256 states in relevant part that "a substance included in schedule II must not be dispensed without the written prescription of a practitioner."

XXIV.

NAC 453.450(1)(a) states in relevant part that "[a] pharmacist may dispense a controlled substance listed in schedule II only pursuant to . . . [a] written prescription . . . that is transmitted by a practitioner or his or her agent by a facsimile machine to a pharmacy . . . ."

XXV.

NAC 639.945 identifies certain actions by a licensee or an employee of a licensee to be unprofessional conduct and conduct contrary to the public interest, including: "Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner."

XXVI.

Pursuant to NAC 639.945(2), “[t]he owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ.”

**FIRST CAUSE OF ACTION**  
**(Wal-mart Pharmacy #10-5269)**

XXVII.

By dispensing a schedule II controlled substance without a written prescription on file, Respondent Wal-mart #10-5269 violated NRS 453.256, which conduct is grounds for discipline pursuant to NRS 639.210(11) and (12), as well as NRS 639.255.

**SECOND CAUSE OF ACTION**  
**(Wal-mart Pharmacy #10-5269)**

XXVIII.

By dispensing a schedule II controlled substance without a written prescription on file, Respondent Wal-mart Pharmacy #10-5269 engaged in unprofessional conduct as defined in NAC 639.945(1)(i), which conduct is grounds for discipline pursuant to NRS 639.210(4) and NRS 639.255.


**THIRD CAUSE OF ACTION**  
**(Wal-mart Pharmacy #10-5269)**

XXIX.

As the pharmacy in which the foregoing violations, or any one of them, occurred, Wal-mart Pharmacy #10-5269 is responsible for the actions of its employees, and thus, is responsible for any violations of its employees of NRS 453.256(1), NAC 453.450(1)(a), which violations are grounds for action pursuant to NRS 453.256 (1), and/or NRS 639.210(4), (11), and/or (12), and NRS 639.255.

Wherefore, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of these respondents.

Signed this <sup>15</sup>15 day of June, 2016.

  
\_\_\_\_\_  
Larry L. Finson, Executive Secretary  
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**

|   |   |                             |
|---|---|-----------------------------|
| <b>NEVADA STATE BOARD OF PHARMACY,</b>          | ) |                             |
|   | ) | <b>CASE NO. 16-001-PH-S</b> |
| <b>Petitioner,</b>                              | ) |                             |
| v.  | ) | <b>STATEMENT TO THE</b>     |
|   | ) | <b>RESPONDENT NOTICE</b>    |
|   | ) | <b>OF INTENDED ACTION</b>   |
| <b>WAL-MART PHARMACY #10-5269</b>               | ) | <b>AND ACCUSATION</b>       |
| <b>Certificate of Registration No. PH01985,</b> | ) | <b>RIGHT TO HEARING</b>     |
|   | ) |                             |
| <b>Respondent.</b>                              | / |                             |

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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.

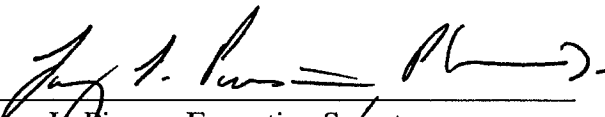
III.

The Board has reserved Wednesday, July 20, 2016, as the date for a hearing on this matter at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., 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 15<sup>th</sup> day of June, 2016.

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

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

|   |   |                             |
|---|---|-----------------------------|
| <b>NEVADA STATE BOARD OF PHARMACY,</b>          | ) | <b>CASE NO. 16-001-PH-S</b> |
|   | ) |                             |
| <b>Petitioner,</b>                              | ) |                             |
| <b>v.</b>                                       | ) | <b>ANSWER AND NOTICE</b>    |
|   | ) | <b>OF DEFENSE</b>           |
| <b>WAL-MART PHARMACY #10-5269</b>               | ) |                             |
| <b>Certificate of Registration No. PH01985,</b> | ) |                             |
|   | ) |                             |
| <b>Respondent.</b>                              | / |                             |

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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 \_\_\_\_\_, 2016.

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Authorized Representative for  
WAL-MART PHARMACY #10-5269

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,** )

**Petitioner,** )

**v.** )

**DANIEL SHALALA, RPH** )  
**Certificate of Registration No. 15615** )

**CHRISTOPHER PETERS, RPH** )  
**Certificate of Registration No. 16325** )

**KELLY GREEN, RPH** )  
**Certificate of Registration No. 10331** )

**PATHWAY SPECIALTY COMPOUNDS** )  
**Certificate of Registration No. PHC02590** )

**Respondents.** /

**CASE NOS. 14-073-RPH-A-S**  
**14-073-RPH-B-S**  
**14-073-RPH-C-S**  
**14-073-PH-S**

**NOTICE OF INTENDED ACTION**  
**AND ACCUSATION**

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, 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 (Board) has jurisdiction over this matter and these respondents because at the time of the events alleged herein, Respondent Daniel Shalala (Mr. Shalala), Certificate of Registration No. 15615, Respondent Christopher Peters (Mr. Peters), Certificate of Registration No. 16325, and Respondent Kelly Green (Mr. Green), Certificate of Registration No. 10331, were each pharmacists licensed by the Board, and Respondent Pathway Specialty Compounds (Pathway) was a pharmacy licensed by the Board.

## **Prior Disciplinary Actions Taken Against Certain Respondents**

### II.

In August 2010, the Board entered a Findings of Fact, Conclusions of Law and Order in the case of *Board of Pharmacy v. Respondent Christopher Peters*, Case No. 10-011-RPH-S. In that 2010 Order, the Board revoked Mr. Peters' Certificate of Registration No. 16325 for violations related to creating and filling fraudulent controlled substance prescriptions for himself. In July 2012, the Board amended its Order and placed Mr. Peters on probation with conditions for a period of ten (10) years. Mr. Peters' pharmacist license was still on probation at the time of the violations alleged here.

### III.

In April 2012, the Board accepted a Stipulation and Order (2012 Order) in the case of *Board of Pharmacy v. Pathway Specialty Compounds*, Case No. 11-092-PH-S. In that 2012 Order, the Board placed Pathway's license on probation for a period of three years, with conditions, for violating the law regarding sterile compounding. Those conditions included training for compounding staff, and the approval by the Board Executive Secretary or Board Counsel of "any new staff conducting activities related to sterile compounding." Pathway's pharmacy license was still on probation at the time of the violations alleged in the instant action.

### IV.

In August 2014, a Board Inspector conducted Pathway's annual pharmacy inspection. The Board Inspector found substantial misconduct and numerous violations that put into question Pathway and its pharmacists' ability to compound safely. Issues the Inspectors found include:

- Expired ingredients in Pathway's inventory.
- Incomplete compounding worksheets and other records of sterile and non-sterile compounding activities;
- Incomplete records regarding the ingredients used in Pathway's compounds;
- Substantial inconsistencies in the expiration dates and lot numbers recorded on the worksheets and documentation for compounded products and the actual expiration dates and lot numbers for the products used.

- Documentation indicating that Pathway compounded with ingredients that would expire before the compounded product's assigned beyond use date (BUD).
- Documentation indicating that Pathway assigned grossly excessive BUDs to compounded sterile products.<sup>1</sup>

#### V.

As a result of the August 2014 inspection, the Board Inspector left Pathway with at least two specific directives: (1) the "Facility will initiate [an] action plan to validate extended beyond use dates of the most commonly dispensed sterile products and provide documentation to BOP by 12/15/2014," and (2) "All CSP (compounded sterile products) not validated with extended beyond use dates will comply with NAC/USP 797 recommendations and standards." Pathway did not implement a corrective action plan addressing the issues identified at the August 2014 inspection.

#### **2014 Complaint and Allegations**

#### VI.

A complaint brought the Board's Inspectors back to Pathway in October 2014. According to the complaint, Pathway hired a marketing representative to market testosterone in special mixes and bulk sale to physicians in the Las Vegas area. The marketing representative requested that the pharmacy compound testosterone injectable samples, which were prepared by a pharmaceutical technician. When the marketing representative failed to produce prescriptions for the medication, pharmacy staff intercepted the medication, impounded it and contacted Board Staff.

#### VII.

While reviewing the compounding worksheet for that testosterone product, the Board Investigator discovered many of the same compounding issues that were supposed to have been addressed in response to the 2012 Stipulation and Order, and again in response to the Board Inspector's instructions following the inspection in August 2014.

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<sup>1</sup> Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a high risk sterile compounded product must not exceed: 24 hours at controlled room temperature 20-25 degrees C, 3 days at cold temperature 2-8 degrees C, and 45 days in a solid frozen state of -10 C or colder. (NAC 639.67067 sub 2.)

### VIII.

Specifically, the compounding worksheet did not identify all of the ingredients used to make the compounded the testosterone product at issue. It did not contain required information that would allow the verification of the expiration dates and lot numbers for some of the ingredients used in the medication. The worksheet revealed that the grapeseed oil used in the compounded medication expired on April 24, 2013—approximately seventeen months earlier. Further, the pharmacy assigned a six-month BUD for the medication of April 5, 2015, when a maximum of three days is allowed. Finally, two of the ingredients used to compound the testosterone (benzyl benoate and benzyl alcohol) had expiration dates in March 2015, weeks before the BUD Pathway assigned for the final product.

### IX.

The errors the Investigator found on that single compounding worksheet prompted him to review the records for other compounded prescriptions. He requested that the pharmacist on duty at the time provide a random sample of other recently compounded prescriptions. The pharmacist, Respondent Mr. Peterson, provided the Investigator with one-hundred and nine (109) compounding worksheets for prescriptions compounded by Pathway during the time period of June 2014, through October 2014 (the "Worksheets").

### X.

The Board Investigator, with the assistance of two Board Inspectors, analyzed the Worksheets and found evidence that Pathway's compounding practices are generally below and not compliant with Nevada compounding regulations and USP 797 standards.

### XI.

Addendum A, attached hereto and incorporated by reference herein, summarizes the issues Board Staff identified in the Worksheets. They include many of the issues mentioned above.

### XII.

Addenda B, C and D, also attached hereto and incorporated by reference herein, summarize the same errors found in the Worksheets specifically by Respondents Mr. Shalala, Mr. Peters and Mr. Green.

XIII.

The summaries attached as Addendum A through D do not address the Investigator's additional discovery that the Worksheets do not accurately reflect the lot numbers or expiration dates of materials used in compounding the subject products.

XIV.

At the time, Pathway attributed some of the missing or inaccurate lot numbers and past-due ingredient expiration dates to its compounding software, Compound Assist. For unknown reasons, the software purportedly stored the initial lot number and expiration date for each ingredient entered into Pathway's materials inventory. The computer would not recognize subsequent data entries, such that when a Pathway employee attempted to record receipt of additional stock of an ingredient that was already in the computer system, the lot numbers and expiration dates did not update. The Worksheets were supposedly wrong in that regard because the software provided inaccurate information.

XV.

Pathway was not able to provide a copy of any sterile and/or non-sterile compounding policies and procedures that were in effect at the time of the alleged violations.

XVI.

In a written statement by Ms. Wild, and by their own admissions, Mr. Shalala, Mr. Peters and Mr. Green received inadequate training and lacked sufficient experience in sterile and non-sterile compounding and the use of the Compound Assist software. They relied on pharmaceutical technician Maribel Acevedo to generate the Worksheets and prepare the compounds.

XVII.

Ms. Acevedo admitted in an interview during the investigation that she does not have any formal training in compounding sterile and non-sterile products. Per her admission, she received some informal training by a pharmaceutical technician at her former place of employment.

XVIII.

Ms. Acevedo admitted that she was not aware that the compounding worksheets had to be completely filled out.

XIX.

Pathway's employees did not, as a matter of course, verify lot numbers or expiration dates listed on the worksheet against the product they were compounding.

XX.

Pathway did not list sterilization procedures on its compounding worksheets.

XXI.

During interviews, Mr. Shalala, Mr. Peters and Mr. Green, each admitted that their worksheets lacked documentation and contained erroneous information. Several worksheets did not contain a pharmacist's signature verifying that the pharmacist had verified the final compounded product.

**FIRST CAUSE OF ACTION**

**Failure to Keep Accurate Records**

(Respondents Daniel Shalala, Christopher Peters, and Kelly Green)

XXII.

By failing to maintain accurate records reflecting the products used, lot numbers, expiration dates, beyond use dates, product sterilization and/or product testing on compounding worksheets and/or finished compounded products, Respondents Mr. Shalala, Mr. Peters, and Mr. Green each violated Nevada Administrative Code (NAC) 639.6701(1)(c), NAC 639.6702, NAC 639.6703, NAC 639.945(1)(i) and/or (m), which violations are grounds for action pursuant to NRS 639.210(4), (11), (12), (17) and/or NRS 639.255.

**SECOND CAUSE OF ACTION**

**Failure to Conduct Required Testing**

(Respondents Daniel Shalala, Christopher Peters, and Kelly Green)

XXIII.

By failing to conduct batch testing of high-risk sterile compounded drug products, Respondents Mr. Shalala, Mr. Peters, and Mr. Green, and each of them, violated NAC 639.67071,

and/or NAC 639.945(1)(i), which violations are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or NRS 639.255.

**THIRD CAUSE OF ACTION**

**Sterilization Technique**

(Respondents Daniel Shalala, Christopher Peters, and Kelly Green)

XXIV.

By failing to ensure that each high-risk sterile compounded drug product they produced was sterilized through filtration, Respondents Mr. Shalala, Mr. Peters, and Mr. Green each violated NAC 639.67071 and/or NAC 639.945(1)(i), which violations are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or NRS 639.255.

**FOURTH CAUSE OF ACTION**

**Managing Pharmacist Responsibilities**

(Respondent Daniel Shalala)

XXV.

As a managing pharmacist who knew of and allowed the foregoing violations, or any one of them, to occur in his pharmacy, Respondent Daniel Shalala violated NAC 639.945(1)(i), which violation is subject to discipline pursuant to NRS 639.210(4), (11), (12), and/or (15), and/or NRS 639.255.

**FIFTH CAUSE OF ACTION**

**Staff Working Outside Scope of Training**

(Pathway Specialty Compounds)

XXVI.

By allowing untrained or inadequately trained pharmacy staff to compound sterile and non-sterile drug products, Pathway Specialty Compounds violated NAC 639.67013 and/or NAC 639.945(1)(i), which violations are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or NRS 639.255.

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**SIXTH CAUSE OF ACTION**  
**Policies and Procedures**  
(Pathway Specialty Compounds)

XXVII.

In failing to establish and maintain policies and procedures for compounding drug products, Pathway Specialty Compounds violated NAC 639.67015 and/or NAC 639.67035, which violations are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or NRS 639.255.

**SEVENTH CAUSE OF ACTION**  
**Pharmacy Responsibility**  
(Pathway Specialty Compounds)

XXVIII.

As the pharmacy in which the violations alleged above occurred, Pathway Specialty Compounds is statutorily responsible for the actions of Respondents Mr. Shalala, Mr. Peters, and Mr. Green as alleged herein, pursuant to NAC 639.945(2), which is grounds for discipline pursuant to NRS 639.210(4), (11) and/or (12), and NRS 639.255.

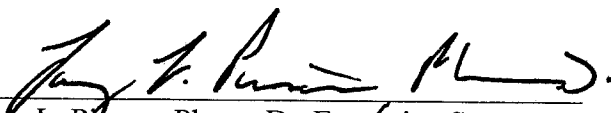
**EIGHTH CAUSE OF ACTION**  
**Failure to Comply with Board Orders**  
(Pathway Specialty Compounds)

XXIX.

By failing to fully comply with the terms and conditions of the Board Order in Case No. 11-092-PH-S, Pathway Specialty Compounds violated Nevada Administrative Code (NAC) 639.945(1)(l), which violation is grounds for action pursuant to Nevada Revised Statute (NRS) 639.210(1) and/or (4), and NRS 639.255.

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

Signed this 11<sup>th</sup> day of March, 2016.

  
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Larry L. Pinson, Pharm.D., 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.

Addendum A

Addendum A