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 22nd 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

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

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 22nd day of March, 2016.

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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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

_____
LISA HARRIS BAKER, R.PH.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WAL-MART PHARMACY #10-5269** **Certificate of Registration No. PH01985,** **Respondents.**	**CASE NO. 16-001-PH-S** **AMENDED 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.

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 15th day of June, 2016.

Larry L. Pinson, 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

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 16-001-PH-S**
Petitioner,	)	**STATEMENT TO THE**
v.	)	**RESPONDENT NOTICE**
	)	**OF INTENDED ACTION**
WAL-MART PHARMACY #10-5269	)	**AND ACCUSATION**
Certificate of Registration No. PH01985,	)	**RIGHT TO HEARING**
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, 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 15th day of June, 2016.

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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 16-001-PH-S**
	)	
Petitioner,	)	
v.	)	**ANSWER AND NOTICE**
	)	**OF DEFENSE**
WAL-MART PHARMACY #10-5269	)	
Certificate of Registration No. PH01985,	)	
	)	
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 _____, 2016.

_____

Authorized Representative for
WAL-MART PHARMACY #10-5269

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	
	)	
Petitioner,	)	**CASE NOS. 14-073-RPH-A-S**
v.	)	**14-073-RPH-B-S**
	)	**14-073-RPH-C-S**
DANIEL SHALALA, RPH	)	**14-073-PH-S**
Certificate of Registration No. 15615	)	
	)	
CHRISTOPHER PETERS, RPH	)	**NOTICE OF INTENDED ACTION**
Certificate of Registration No. 16325	)	**AND ACCUSATION**
	)	
KELLY GREEN, RPH	)	
Certificate of Registration No. 10331	)	
	)	
PATHWAY SPECIALTY COMPOUNDS	)	
Certificate of Registration No. PHC02590	)	
	)	
Respondents.	/	

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. [1]

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.

[1] 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 Addendam 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.

EIGTH 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 11th day of March, 2016.

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

Pathway Specialty Pharmacy Recap
Inaccuracies identified on 109 Compounding Worksheets

Color Coding	Issue Identified	Quantity	Description
	"SR " Sustained Release	11 of 109 Worksheets	Pathway was not able to supply any documentation supporting who provided the "SR" recipe along with the study results indicating duration of action and amount of medication released per hour. Pathway never sent compounded product to a lab for testing.
	Incomplete Compounding Worksheets	101 of 109 Worksheets	Worksheets failed to document all the ingredients used in compounding the prescriptions along with required calculations.
	Product Expired prior to Compounding "Log Entry Date"	85 of 109 Worksheets	Worksheets listed expired product on the date it was compounded. 132 expired products were listed on the worksheets.
	Product Expired prior to Beyond Use Date	62 of 109 Worksheets	Products that were in date at the time the prescription was compounded however, would expire prior to the Beyond Use Date recorded. 90 products were identified from the worksheets.
	Beyond Use Date Errors	52 of 109 Worksheets	Worksheets were given inaccurate Beyond Use Dates. 38 of the BUD's that were in error involved High Risk injectable's that were given 1 month to 1 year that should have been 24 hours at room temperature or 3 days refrigerated. 4 worksheets stated in the instructions "Expiration date is 1 month from compounded date" in which it was given 3 months.
	Bacteriostatic Water Compounded by Pathway	17 of 109 Worksheets	Worksheets contained Bacteriostatic Water used for High Risk injectable's that was compounded by Pathway who gave expiration dates of 6 months instead of 24 hours / 3 days refrigerated.
	PH Adjustments Undocumented	9 of 109 Worksheets	Worksheets indicated a required PH adjustments of which none of the sheets showed any evidence the PH adjustment required was done.
	SWFI Calculations Undocumented	5 of 109 Worksheets	Worksheet indicates a data entry field for the volume of sterile water to be used in the compounding process that was not documented.
	Bubble Point Testing Not Performed	20 of 109 Worksheets	4 Worksheets specifically indicated Bubble Point Testing in the directions. The remaining sheets identify the use of a .22 Micron Filters which normally are used in sterilization by filtration. No sterilization method was indicated on the worksheet.
	Pharmacist Pre-Checks Undocumented	65 of 109 Worksheets	Pharmacist failed to inspect and either approve or reject, without limitation, each component, container, closure, label and other material used in the process of compounding each drug product.

Addendum B

Addendum B

Pathway Specialty Pharmacy Recap for Kelly Green
Inaccuracies identified on 15 Compounding Worksheets

Color Coding	Issue Identified	Quantity	Description
	"SR " Sustained Release	0 of 17 Worksheets Identified In the Sampling	Pathway was not able to supply any documentation supporting who provided the "SR" recipe along with the study results indicating duration of action and amount of medication released per hour. Pathway never sent compounded product to a lab for testing.
	Incomplete Compounding Worksheets	17 of 17 Worksheets	Worksheets failed to document all the ingredients used in compounding the prescriptions along with required calculations.
	Product Expired prior to Compounding "Log Entry Date"	16 of 17 Worksheets	Worksheets listed expired product on the date it was compounded. 23 expired products were listed on the worksheets.
	Product Expired prior to Beyond Use Date	11 of 17 Worksheets	Products that were in date at the time the prescription was compounded however, would expire prior to the Beyond Use Date recorded. 15 products were identified from the worksheets. .
	Beyond Use Date Errors	12 of 17 Worksheets	Worksheets were given inaccurate Beyond Use Dates. 11 of the BUD's that were in error involved High Risk injectable's that were given 1 month to 6 months that should have been 24 hours at room temperature or 3 days refrigerated
	Bacteriostatic Water Compounded by Pathway	4 of 17 Worksheets	Worksheets contained Bacteriostatic Water used for High Risk injectable's that was compounded by Pathway who gave expiration dates of 6 months instead of 24 hours/3 days refrigerated.
	PH Adjustments Undocumented	6 of 17 Worksheets	Worksheets indicated a required PH adjustments of which none of the sheets showed any evidence the PH adjustment required was done.
	SWFI Calculations Undocumented	3 of 17 Worksheets	Worksheet indicates a data entry field for the volume of sterile water to be used in the compounding process that was not documented.
	Bubble Point Testing Not Performed	10 of 17 Worksheets	1 Worksheet specifically indicated Bubble Point Testing in the directions. The remaining sheets identify the use of a .22 Micron Filters which normally are used in sterilization by filtration. No sterilization method was indicated on the worksheet.
	Pharmacist Pre-Checks Undocumented	15 of 17 Worksheets	Pharmacist failed to inspect and either approve or reject, without limitation, each component, container, closure, label and other material used in the process of compounding each drug product.

Addendum C

Addendum C

Pathway Specialty Pharmacy Recap for Christopher Peters
Inaccuracies identified on 34 Compounding Worksheets

Color Coding	Issue Identified	Quantity	Description
	"SR " Sustained Release	6 of 32 Worksheets	Pathway was not able to supply any documentation supporting who provided the "SR" recipe along with the study results indicating duration of action and amount of medication released per hour. Pathway never sent compounded product to a lab for testing.
	Incomplete Compounding Worksheets	27 of 32 Worksheets	Worksheets failed to document all the ingredients used in compounding the prescriptions along with required calculations.
	Product Expired prior to Compounding "Log Entry Date"	26 of 32 Worksheets	Worksheets listed expired product on the date it was compounded. 48 expired products were listed on the worksheets.
	Product Expired prior to Beyond Use Date	15 of 32 Worksheets	Products that were in date at the time the prescription was compounded however, would expire prior to the Beyond Use Date recorded. 25 products were identified from the worksheets.
	Beyond Use Date Errors	11 of 32 Worksheets	Worksheets were given inaccurate Beyond Use Dates. 7 of the BUD's that were in error involved High Risk injectable's that were given 1 month to 6 months that should have been 24 hours at room temperature or 3 days refrigerated. 1 worksheet stated in the instructions "Expiration date is 1 month from compounded date" in which it was given 3 months.
	Bacteriostatic Water Compounded by Pathway	2 of 32 Worksheets	Worksheets contained Bacteriostatic Water used for High Risk injectable's that was compounded by Pathway who gave expiration dates of 6 months instead of 24 hours/3 days refrigerated.
	PH Adjustments Undocumented	1 of 32 Worksheets	Worksheets indicated a required PH adjustments of which none of the sheets showed any evidence the PH adjustment required was done.
	SWFI Calculations Undocumented	1 of 32 Worksheets	Worksheet indicates a data entry field for the volume of sterile water to be used in the compounding process that was not documented.
	Bubble Point Testing Not Performed	3 of 32 Worksheets	1 Worksheet specifically indicated Bubble Point Testing in the directions. The remaining sheets identify the use of a .22 Micron Filters which normally are used in sterilization by filtration. No sterilization method was indicated on the worksheet.
	Pharmacist Pre-Checks Undocumented	0 of 32 Worksheets Identified in the Sampling	Pharmacist failed to inspect and either approve or reject, without limitation, each component, container, closure, label and other material used in the process of compounding each drug product.

Addendum D

Addendum D

Pathway Specialty Pharmacy Recap for Daniel Shalala
Inaccuracies identified on 60 Compounding Worksheets

Color Coding	Issue Identified	Quantity	Description
	"SR " Sustained Release	5 of 60 Worksheets	Pathway was not able to supply any documentation supporting who provided the "SR" recipe along with the study results indicating duration of action and amount of medication released per hour. Pathway never sent compounded product to a lab for testing.
	Incomplete Compounding Worksheets	57 of 60 Worksheets	Worksheets failed to document all the ingredients used in compounding the prescriptions along with required calculations.
	Product Expired prior to Compounding "Log Entry Date"	43 of 60 Worksheets	Worksheets listed expired product on the date it was compounded. 61 expired products were listed on the worksheets.
	Product Expired prior to Beyond Use Date	36 of 60 Worksheets	Products that were in date at the time the prescription was compounded however, would expire prior to the Beyond Use Date recorded. 50 products were identified from the worksheets.
	Beyond Use Date Errors	29 of 60 Worksheets	Worksheets were given inaccurate Beyond Use Dates. 20 of the BUD's that were in error involved High Risk injectable's that were given 1 month to 1 year that should have been 24 hours at room temperature or 3 days refrigerated. 3 worksheets stated in the instructions "Expiration date is 1 month from compounded date" in which it was given 3 months.
	Bacteriostatic Water Compounded by Pathway	11 of 60 Worksheets	Worksheets contained Bacteriostatic Water used for High Risk injectable's that was compounded by Pathway who gave expiration dates of 6 months instead of 24 hours room temperature or 3 days refrigerated.
	PH Adjustments Undocumented	2 of 60 Worksheets	Worksheets indicated a required PH adjustments of which none of the sheets showed any evidence the PH adjustment required was done.
	SWFI Calculations Undocumented	1 of 60 Worksheets	Worksheet indicates a data entry field for the volume of sterile water to be used in the compounding process that was not documented.
	Bubble Point Testing Not Performed	7 of 60 Worksheets	2 Worksheets specifically indicated Bubble Point Testing in the directions. The remaining sheets identify the use of a .22 Micron Filters which normally are used in sterilization by filtration. No sterilization method was indicated on the worksheet.
	Pharmacist Pre-Checks Undocumented	50 of 60 Worksheets	Pharmacist failed to inspect and either approve or reject, without limitation, each component, container, closure, label and other material used in the process of compounding each drug product.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**STATEMENT TO THE RESPONDENT**
	)	**NOTICE OF INTENDED ACTION**
Petitioner,	)	**AND ACCUSATION**
v.	)	**RIGHT TO HEARING**
	)	
DANIEL SHALALA, RPH	)	**CASE NO. 14-073-RPH-A-S**
Certificate of Registration No. 15615	)	
	)	
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 (Board) 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 Board 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 Board 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, April 13, 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 11th day of March 2016.

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

RSPN
MICHAEL L. PETERS, ESQ.
Nevada Bar No. 0989
601 South 10th Street, Suite 201
Las Vegas, Nevada 89101
(702) 894-4100
Attorney for Respondent,
Daniel Shalala

NEVADA STATE BOARD of PHARMACY, a Nevada corporation,

Plaintiff,

vs.

DANIEL SHALALA RPH CERTIFICATE of REGISTRATION NO. 15615

Respondent.

ANSWER TO SPECIFIC ALLEGATIONS CONTAINED IN THE NOTICE OF INTENDED ACTION AND ACCUSATION

TO: Paul Edward, Nevada Board of Pharmacy Attorney

DANIEL SHALALA, Respondent, does hereby respond as follows-

PARAGRAPH I

Admit.

PARAGRAPH II

Respondent is without knowledge and therefore denies.

PARAGRAPH III

Respondent is without knowledge and therefore denies.

PARAGRAPH IV

Said allegations are vague, ambiguous, and incorrect, and therefore is denied.

PARAGRAPH V

Respondent is without knowledge and therefore, denies.

///

PARAGRAPH VI

Respondent is without knowledge and therefore, denies.

PARAGRAPH VII

Respondent is without knowledge and therefore, denies.

PARAGRAPH VIII

Respondent is without knowledge and therefore, denies.

PARAGRAPH IX

Respondent is without knowledge and therefore denies.

PARAGRAPH X

Respondent is without knowledge and therefore, denies.

PARAGRAPH XI

Said allegation is vague and ambiguous and therefore, denied.

PARAGRAPH XII

Said allegation is vague and ambiguous and therefore, denied.

PARAGRAPH XIII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XIV

Admit, however, Respondent had no control over this problem, and personally knew that the materials were not expired, because he was personally involved with the day to day ordering of ingredients for Pathway.

PARAGRAPH XV

Respondent is without knowledge and therefore, denies.

PARAGRAPH XVI

Respondent admits he relied upon Ms. Acevedo to generate the worksheets. Respondent admits he relied upon Ms. Acevedo to prepare the compounds, but it is proper and standard practice to do so. Also, Respondent would oversee her work. Respondent admits he did

not know how to use Compound Assist Software, but asserts he had no duty to know how to use it.

PARAGRAPH XVII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XVIII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XIX

Deny, because of the software problem and his personal knowledge of the ongoing purchase of ingredients he knew none of the ingredients were expired.

PARAGRAPH XX

Admit, however Respondent knew that the sterilization procedures were followed because he observed it being processed, and he knew Ms. Acevedo was aware and well trained in the process. Also, it was her habit and custom to properly follow sterilization procedures.

PARAGRAPH XXI

Admit, the first sentence, however, Respondent knew that the product being produced was correctly, properly, and timely made. Regarding the second sentence, Respondent is without knowledge and therefore denies.

PARAGRAPH XXII

Deny.

PARAGRAPH XXIII

Deny.

PARAGRAPH XXIV

Deny.

PARAGRAPH XXV

Respondent is without knowledge and therefore, denies.

PARAGRAPH XXVI

Respondent is without knowledge and therefore, denies.

PARAGRAPH XXVII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XXVIII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XXIV

Respondent is without knowledge and therefore, denies.

DATED this 5 day of April, 2016.

MICHAEL L. PETERS, ESQ.
On Behalf of Daniel Shalala
Respondent

RSPN
MICHAEL L. PETERS, ESQ.
Nevada Bar No. 0989
601 South 10th Street, Suite 201
Las Vegas, Nevada 89101
(702) 894-4100
Attorney for Respondent,
CHRISTOPHER J. PETERS

NEVADA STATE BOARD of PHARMACY, a Nevada corporation,

Plaintiff,

vs.

CHRISTOPHER PETERS RPH CERTIFICATE of REGISTRATION NO. 16325

Respondent.

ANSWER TO SPECIFIC ALLEGATIONS CONTAINED IN THE NOTICE OF INTENDED ACTION AND ACCUSATION

TO: Paul Edward, Nevada Board of Pharmacy Attorney

CHRISTOPHER J. PETERS, Respondent, does hereby respond as follows-

PARAGRAPH I

Admit.

PARAGRAPH II

Admit.

PARAGRAPH III

Respondent is without knowledge and therefore denies.

PARAGRAPH IV

Said allegations are vague, ambiguous, and incorrect, and therefore is denied.

PARAGRAPH V

Respondent is without knowledge and therefore, denies.

PARAGRAPH VI

Respondent is without knowledge and therefore, denies.

PARAGRAPH VII

Respondent is without knowledge and therefore, denies.

PARAGRAPH VIII

Respondent is without knowledge and therefore, denies.

PARAGRAPH IX

Deny first sentence. Admit the rest of paragraph.

PARAGRAPH X

Respondent is without knowledge and therefore, denies.

PARAGRAPH XI

Said allegation is vague and ambiguous and therefore, denied.

PARAGRAPH XII

Said allegation is vague and ambiguous and therefore, denied.

PARAGRAPH XIII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XIV

Admit, however, Respondent had no control over this problem, and personally knew that the materials were not expired, because he was personally involved with the ordering of ingredients for Pathway.

PARAGRAPH XV

Respondent is without knowledge and therefore, denies.

PARAGRAPH XVI

Respondent admits he relied upon Ms. Acevedo to generate the worksheets. Respondent admits he relied upon Ms. Acevedo to prepare the compounds, but it is proper and standard practice to do so. Also, Respondent would oversee her work. Respondent admits he did not know how to use Compound Assist Software, but asserts he had no

duty to know how to use it.

PARAGRAPH XVII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XVIII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XIX

Deny, because of the software problem and his personal knowledge of the ongoing purchase of ingredients he knew none of the ingredients were expired.

PARAGRAPH XX

Admit, however Respondent knew that the sterilization procedures were followed because he observed it being processed, and he knew Ms. Acevedo was aware and well trained in the process. Also, it was her habit and custom to properly follow sterilization procedures.

PARAGRAPH XXI

Admit, the first sentence, however, Respondent knew that the product being produced was correctly, properly, and timely made. Regarding the second sentence, Respondent is without knowledge and therefore denies.

PARAGRAPH XXII

Deny.

PARAGRAPH XXIII

Deny.

PARAGRAPH XXIV

Deny.

PARAGRAPH XXV

Respondent is without knowledge and therefore, denies.

///

PARAGRAPH XXVI

Respondent is without knowledge and therefore, denies.

PARAGRAPH XXVII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XXVIII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XXIV

Respondent is without knowledge and therefore, denies.

DATED this 5 day of April, 2016.

MICHAEL L. PETERS, ESQ.
On Behalf of Christopher J. Peters
Respondent

RSPN
MICHAEL L. PETERS, ESQ.
Nevada Bar No. 0989
601 South 10th Street, Suite 201
Las Vegas, Nevada 89101
(702) 894-4100
Attorney for Respondent,
Pathway Speciality Compounds

NEVADA STATE BOARD of PHARMACY, a Nevada corporation,

Plaintiff,

vs.

PATHWAY SPECIALTY COMPOUNDS CERTIFICATE of REGISTRATION NO. PH02590

Respondent.

ANSWER TO SPECIFIC ALLEGATIONS CONTAINED IN THE NOTICE OF INTENDED ACTION AND ACCUSATION

TO: Paul Edward, Nevada Board of Pharmacy Attorney

PATHWAY SPECIALTY COMPOUNDS, Respondent, does hereby respond as follows-

PARAGRAPH I

Admit.

PARAGRAPH II

Respondent is without any direct knowledge and therefore denies.

PARAGRAPH III

Admit.

PARAGRAPH IV

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

///

PARAGRAPH V

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH VI

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH VII

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH VIII

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH IX

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH X

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XI

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XII

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XIII

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

///

PARAGRAPH XIV

Admit, that some problems identified resulted from computer software issues. The rest of said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XV

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XVI

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XVII

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XVIII

Respondent is without knowledge and therefore, denies.

PARAGRAPH XIX

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XX

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XXI

Respondent is without knowledge and therefore denies this sentence.

PARAGRAPH XXII

Paragraph XXII is not directed at this respondent but based upon good faith knowledge and belief, denies.

///

PARAGRAPH XXIII

Paragraph XXIII is not directed at this respondent but based upon good faith knowledge and belief, denies.

PARAGRAPH XXIV

Paragraph XXIV is not directed at this respondent but based upon good faith knowledge and belief, denies.

PARAGRAPH XXV

Paragraph XXV is not directed at this respondent but based upon good faith knowledge and belief, denies.

PARAGRAPH XXVI

Deny.

PARAGRAPH XXVII

Deny.

PARAGRAPH XXVIII

Said allegations are vague, ambiguous, and/or incorrect, and therefore is denied.

PARAGRAPH XXIV

Deny.

DATED this 5 day of April, 2016.

Michael L. Peters

MICHAEL L. PETERS, ESQ.
On Behalf of Pathway Specialty Compounds.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TINA RIZZOLO, RPH** **Certificate of Registration No. 17665,** **LUCAS MEYERS, RPH** **Certificate of Registration No. 16064,** **WALGREENS PHARMACY #3922** **Certificate of Registration No. PHN01127, and** **WALGREENS MAIL SERVICE, INC.** **Certificate of Registration No. PH01964,** **Respondents.** /	**CASE NO. 15-028-RPH-A-S** **CASE NO. 15-028-RPH-B-S** **CASE NO. 15-028-PH-S** **CASE NO. 15-028-PH-O** **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 because at the time of the events alleged herein, Respondents Tina Rizzolo (Ms. Rizzolo), Certificate of Registration No. 17665, and Lucas Meyers (Mr. Meyers), Certificate of Registration No. 16064, were pharmacists licensed with the Board, and Respondents Walgreens Pharmacy #3922 (Walgreens), Certification of Registration No. PHN01127, and Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, were pharmacies licensed with the Board.

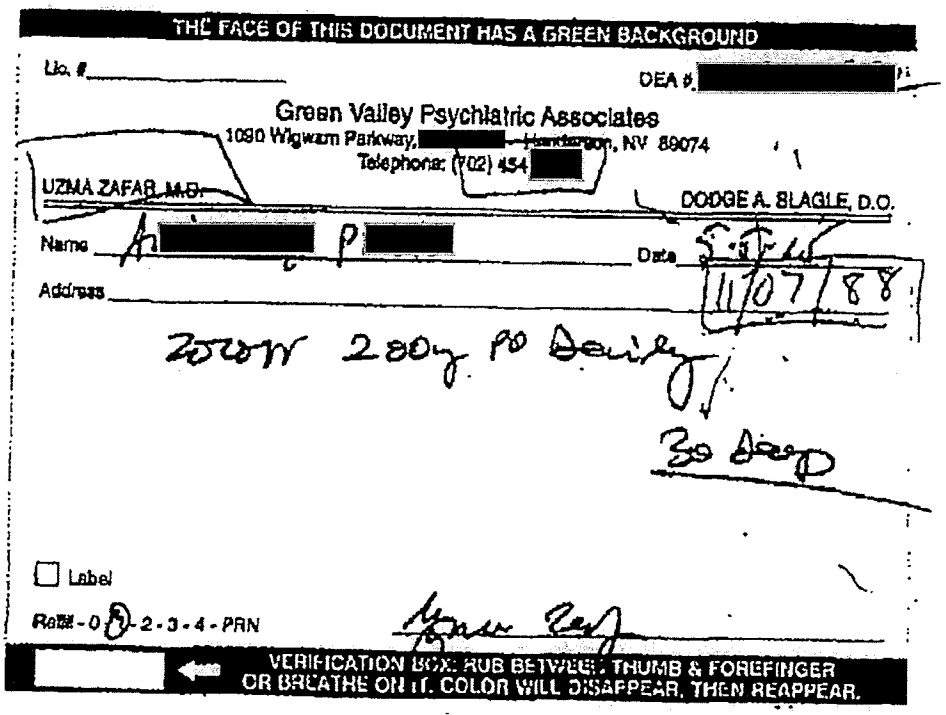
II.

Walgreens Mail Service, Inc. is a work shifting operation located in Orlando, Florida. The facility provides support to Walgreens' retail pharmacies in Nevada. At the time of the

events alleged herein, it provided data verification support to five Walgreens' pharmacies in Las Vegas, Nevada, including Respondent Walgreens Pharmacy #3922.

III.

On May 5, 2015, patient A.P. saw his physician, who prescribed a quantity of thirty (30) Zoloft tablets with instructions to take 200 mg. by mouth daily. The prescription appears as follows:


THE FACE OF THIS DOCUMENT HAS A GREEN BACKGROUND

Lic. #

DEA #

Green Valley Psychiatric Associates

1090 Wigwam Parkway, [redacted], NV 89074

Telephone: (702) 454-[redacted]

UZMA ZAFAR, M.D.

DODGE A. SLAGLE, D.O.

Name [redacted]

Date 11/07/88

Address

200mg 200mg PO Daily

30 Disp

☐ Label

Refill - 0 - 1 - 2 - 3 - 4 - PRN

VERIFICATION BOX: RUB BETWEEN THUMB & FOREFINGER OR BREATHE ON IT. COLOR WILL DISAPPEAR, THEN REAPPEAR.

IV.

Walgreens #3922 accepted the prescription at the pharmacy drive-thru window on May 5, 2015. It filled the prescription that day, and dispensed it to A.P. through the drive through on May 7, 2015.

V.

A.P. ingested one tablet of the dispensed medication on May 8, 2015, per his doctor's instructions. He later discovered that the label on the prescription bottle indicated *Zocor* 20 mg. tablets, rather than the *Zoloft 200 mg.* tablets his physician prescribed.

VI.

A.P. telephoned Walgreens and verified that it dispensed the wrong medication. He returned the medication to Walgreens, which replaced it with the correct medication. A.P. reported no negative impact from ingesting the medication Walgreens initially dispensed.

VII.

According to pharmacy records, the filling error originated with pharmaceutical technician Noelle Mallari (Ms. Mallari), who performed the data entry for A.P.'s prescription (Rx #3094107-3922) at Walgreens #3922.[1]

VIII.

During data entry, Ms. Mallari read the prescription as calling for *Zocor 200 mg.* tablets, rather than the *Zoloft 200 mg.* tablets P.A.'s doctor prescribed. Zocor does not come in 200 mg. tablets, so Ms. Mallari instead selected Zocor 20 mg. tablets.

IX.

Ms. Mallari sent the prescription data into the data entry verification queue for approval by a pharmacist.

X.

Ellen Wagner (Ms. Wagner) is a registered pharmacist in Florida. She is not licensed to practice pharmacy in Nevada. She is employed by Respondent Walgreens Mail Service, Inc. in Florida.

XI.

At the facility in Florida, Ms. Wagner retrieved the data for Rx #3094107-3922 from the queue to perform data verification. Ms. Wagner failed to detect the data entry error and verified Zocor 20 mg. tablets as accurate in lieu of the Zoloft 200 mg. tablets that P.A.'s

[1] The *Audit/Board of Pharmacy Inspection Report Fill History Entered By* field records E. Wagner (Ellen Wagner) for Rx #3094107-2. Walgreens' transactional data indicates that E. Wagner updated the prescriber field subsequent to Ms. Mallari performing data entry. The system records the name of the last individual who adjusted the field.

physician prescribed. After verifying the data as accurate, Ms. Wagner sent the prescription to the queue for filling in Nevada by Walgreens #3922.

XII.

Back at Walgreens #3822, pharmaceutical technician Courtney Watkins retrieved Rx #3094107-3922 from the queue. She filled the prescription with simvastatin (generic for Zocor) 20 mg. tablets, and staged it for the pharmacist's final product review.

XIII.

Pharmacist Lucas Meyers performed the final product verification at Walgreens #3922. He did not detect that the prescription bottle contained simvastatin 20 mg. tablets, instead of the Zoloft 200 mg. tablets P.A.'s doctor prescribed. Without looking at the original prescription or image of the prescription available to him, Mr. Meyers verified and approved the prescription as accurate and complete. He staged the final product for customer pickup.

XIV.

In a written statement, Mr. Meyers explained that under Walgreen's model, his duty is limited to verifying that the product in the vial matches the information on the label and leaflet, even if they do not match the prescription. In this case, the label and leaflet do not match the prescription, as they were generated based on the incorrect data verified by Ms. Wagner at the Florida facility.

XV.

Walgreens #3922 has no mandatory procedure to detect a data entry or verification error by the Florida work shifting facility and/or an out-of-state pharmacist after data verification is complete.

XVI.

Pharmacist Tina Rizzolo's initials are recorded on the Audit/Board of Pharmacy Inspection Report documenting that patient consultation was completed. Ms. Rizzolo did not detect the medication error during counseling.

XVII.

A.P. alleges that counseling was not provided at the pharmacy drive-thru window for Rx #3094107-3922. He informed the Board Investigator that he never receives counseling when he utilizes Walgreens pharmacy drive-thru window.

XVIII.

Walgreens was not able to produce a record of the errant prescription label because Mr. Meyers deleted the errant prescription from A.P.'s patient profile, rather than closing the prescription. The counseling log was also electronically removed from the store level view when the prescription was deleted.

FIRST CAUSE OF ACTION
(Respondent Lucas Meyers)

XIX.

In failing to strictly follow the instructions of A.P.'s physician by verifying and dispensing a prescription for *simvastatin 20 mg. tablets (generic Zocor)*, rather than the *Zoloft 200 mg. tablets* the patient's doctor prescribed, Mr. Meyers violated NAC 639.945(1)(d) and/or (i), which violations are grounds for action pursuant to NRS 639.210(4), (11), and/or (12), and NRS 639.255.

SECOND CAUSE OF ACTION
(Respondent Lucas Meyers)

XX.

In failing to maintain a recordkeeping system that would allow for readily retrievable prescription records for patient A.P.'s prescription, Mr. Meyers violated NRS 639.210(4) and/or (17), NRS 639.236, NAC 639.482, NAC 639.706 and/or NAC 639.945(1)(h) and/or (i), which violations are grounds for action pursuant to NRS 639.210(4) and (17) and/or NRS 639.255.

THIRD CAUSE OF ACTION
(Respondent Tina Rizzolo)

XXI.

In failing to provide adequate counseling for A.P.'s new prescription, which may have detected the medication error, Ms. Rizzolo violated NRS 639.266(1) and NAC 639.707(1) and (2), as well as NAC 639.945(1)(i), which violations are grounds for action pursuant to NRS 639.210(4), (11) and/or (12), and under NRS 639.255.

FOURTH CAUSE OF ACTION
(Respondent Walgreens Pharmacy #3922)

XXII.

As the pharmacy in which the foregoing alleged violations occurred, Walgreens Pharmacy #3922 is responsible for the actions of its employees, Respondents Lucas Meyers and Tina Rizzolo, 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.

FIFTH CAUSE OF ACTION
(Respondent Walgreens Mail Service, Inc.)

XXIII.

As the pharmacy in which the violations alleged herein occurred, Walgreens Mail Service, Inc. is responsible, pursuant to NAC 639.945(2), for the unprofessional conduct of its employee, Ellen Wagner. That conduct includes Ms. Wagner's:

(1) failure to strictly follow the instructions of the prescriber and verifying *simvastatin 20 mg. tablets (generic Zocor)* as the correct medication, instead of the *Zoloft 200 mg. tablets* the physician prescribed, (*see* NAC 639.945(1)(d) and/or (i)); and

(2) failure to confer with A.P.'s physician to verify the medication name and strength, which are illegible and subject to question here. *See* (NAC 639.945(1)(e). This respondent is therefore subject to discipline under NRS 639.210(4), (11) and (12), and NRS 639.255.

Therefore, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses and/or certificates of registration of these respondents.

Signed this 9th day of December, 2015.

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

NOTICE TO RESPONDENT(S)

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,	)	**CASE NO. 15-028-RPH-B-S**
	)	
Petitioner,	)	
	)	**STATEMENT TO THE**
v.	)	**RESPONDENT NOTICE**
	)	**OF INTENDED ACTION**
LUCAS MEYERS, RPH	)	**AND ACCUSATION**
Certificate of Registration No. 16064,	)	**RIGHT TO HEARING**
	/	
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, 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 9th day of December, 2015.

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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 15-028-RPH-B-S**
Petitioner,	)	
	)	**ANSWER AND NOTICE**
v.	)	**OF DEFENSE**
LUCAS MEYERS, RPH	)	
Certificate of Registration No. 16064,	)	
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 December, 2015.

_____
LUCAS MEYERS, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	**CASE NO. 15-028-RPH-A-S**
	CASE NO. 15-028-RPH-B-S
Petitioner,	**CASE NO. 15-028-PH-S**
v.	**CASE NO. 15-028-PH-O**
TINA RIZZOLO, RPH **Certificate of Registration No. 17665,**	
	STIPULATED FACTS
LUCAS MEYERS, RPH **Certificate of Registration No. 16064,**	
WALGREENS PHARMACY #3922 **Certificate of Registration No. PHN01127, and**	
WALGREENS MAIL SERVICE, INC. **Certificate of Registration No. PH01964,**	
Respondents. /	

S. PAUL EDWARDS, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondents Tina Rizzolo (Ms. Rizzolo), Certificate of Registration No. 17665, Walgreens Pharmacy #3922 (Walgreens #3922), Certification of Registration No. PHN01127, and Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, (collectively Respondents), represented by William J. Stilling of Parsons Behle & Latimer,

HEREBY STIPULATE AND AGREE TO THE FOLLOWING FACTS:

1. Walgreens Mail Service, Inc. is a Nevada licensed mail service pharmacy (certificate of registration PH01964) located in Orlando, Florida. The facility provides support to Walgreens' retail pharmacies in Nevada by shifting work load.

2. At the time of the events alleged herein (May 5, 2015 through May 8, 2015), Walgreens Mail Service, Inc. provided data verification support to five Walgreens' pharmacies in Las Vegas, Nevada, including Respondent Walgreens Pharmacy #3922.

3. On May 5, ~~205~~ 2015, Walgreens #3922 accepted a prescription through its drive-thru window for patient AP for thirty (30) Zoloft 200 mg. tablets with instructions to take 200 mg. by mouth daily.

4. Walgreens Pharmacy #3922 filled AP's prescription with Zocor 20 mg. instead of Zoloft 200 mg.

5. AP's prescription was filled as follows.

   a. Pharmaceutical technician Noelle Mallari (Ms. Mallari) performed the data entry for AP's prescription (Rx #3094107-3922) at Walgreens #3922. Ms. Mallari incorrectly entered the prescription as Zocor 20 mg. tablets, rather than Zoloft 200 mg. tablets prescribed by PA's physician.

   b. Ms. Mallari sent the prescription data into the data entry verification queue for approval by a pharmacist.

   c. Ellen Wagner (Ms. Wagner) is a pharmacist licensed in Florida and an employee of Walgreens Mail Service, Inc. Ms. Wagner retrieved the data for Rx #3094107-3922 from the queue to perform data verification. Ms. Wagner failed to detect the data entry error and verified Zocor 20 mg. tablets as accurate. After verifying the data as accurate, Ms. Wagner sent the prescription to the queue for filling in Nevada by Walgreens #3922.

d. At Walgreens #3922, pharmaceutical technician Courtney Watkins retrieved Rx #3094 I 07-3922 from the queue. She filled the prescription with simvastatin (generic for Zocor) 20 mg. tablets and staged it for the pharmacist to conduct the final product verification.

e. Pharmacist Lucas Meyers performed the final product verification at Walgreens #3922 to verify the label, leaflet, and product match. He staged the final product for customer pickup.[1]

f. On May, 7, 2015, AP picked up his prescription at Walgreens #3922 drive-thru window. Pharmacist Tina Rizzolo documented that she completed patient consultation for AP's prescription.

6. AP received simvastatin 20 mg. (Zocor generic) tablets.

7. AP ingested one tablet of the dispensed medication on May 8, 2015, per his doctor's instructions. After he discovered that the label on the prescription bottle indicated Zocor 20 mg. rather than Zoloft 200 mg., AP telephoned Walgreens and verified that the wrong medication was dispensed. Walgreens personnel then dispensed Zoloft 200 mg. to AP.

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[1] In a written statement, Mr. Meyers explained: "My duties for product verification are to match the label, leaflet and product to each other . . . ." All parties agree that Mr. Myers did not write "even if they do not match the prescription" as alleged in Paragraph XIV of the Notice of Intended Action and Accusation.

8. AP reported no negative impact from ingesting Zocor 20 mg.

Signed this 13 day of January, 2016

S. PAUL EDWARDS, Esq.
General Counsel – Board of Pharmacy

Signed this 14 day of January, 2016

WILLIAM J. STILLING
PARSONS BEHLE & LATIMER
Counsel for Respondents

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. TINA RIZZOLO, RPH Certificate of Registration No. 17665, LUCAS MEYERS, RPH Certificate of Registration No. 16064, WALGREENS PHARMACY #3922 Certificate of Registration No. PHN01127, and WALGREENS MAIL SERVICE, INC. Certificate of Registration No. PH01964, Respondents.	)	CASE NO. 15-028-RPH-A-S CASE NO. 15-028-RPH-B-S CASE NO. 15-028-PH-S CASE NO. 15-028-PH-O STIPULATION AND ORDER

S. PAUL EDWARDS, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondents Tina Rizzolo (Ms. Rizzolo), Certificate of Registration No. 17665, Lucas Meyers (Mr. Meyers), Certificate of Registration No. 16064, Walgreens Pharmacy #3922 (Walgreens #3922), Certification of Registration No. PHN01127, and Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, (collectively Respondents), represented by William J. Stilling of Parsons Behle & Latimer,

HEREBY STIPULATE AND AGREE THAT:

1. The Board has jurisdiction over these matters.

2. The Board served a Notice of Intended Action and Accusation (Accusation) on each of the

Respondents on or about December 10, 2015, which each Respondent received.

3. Respondents, and each of them, are fully aware of their right to seek the advice of counsel in this matter, and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondents, and each of them, are fully aware of their right to a hearing on the matters alleged in the Accusation, their right to reconsideration, their right to appeal, and any and all other rights which may be accorded to them pursuant to the Nevada Administrative Procedure Act and the Nevada Pharmacy Act.

5. Conditioned on the Board's acceptance of this Stipulation, and with the exception of the right to challenge any determination that any Respondent failed to comply with the provisions of this Stipulation, Respondents, and each of them, hereby freely and voluntarily waive their rights to a hearing, reconsideration, appeal, and any and all other rights that may be accorded to them by the Nevada Administrative Procedure Act and the Nevada Pharmacy Act.

6. Respondents, and each of them, admit that evidence exists, and that such evidence could be presented at a hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*, that:

a. In failing to maintain a recordkeeping system and/or records that would allow for readily retrievable prescription records for patient A.P.'s prescription, Mr. Meyers violated NRS 639.210(4) and (17), NRS 639.236, NAC 639.482, NAC 639.706 and NAC 639.945(1)(i), which violations are grounds for action pursuant to NRS 639.255.

b. In failing to provide adequate counseling on the patient's new prescription, Respondent Tina Rizzolo violated NRS 639.266(1) and NAC 639.707(1) and (2), as well as NAC 639.945(1)(i), which

violations are grounds for action pursuant to NRS 639.255.

c. As the pharmacy in which Florida pharmacist Ellen Wagner, R.Ph. failed to strictly follow the instructions of A.P.'s physician and verified *simvastatin 20 mg. tablets (generic Zocor)* as the correct medication, instead of the *Zoloft 200 mg. tablets* the physician prescribed, Walgreens Mail Service, Inc. is responsible, pursuant to NAC 639.945(2), for the unprofessional conduct of its employee, and is therefore subject to discipline under NRS 639.255.

7. The foregoing admissions are for the purposes of this proceeding only, and shall have no force or effect in any other case or proceeding before the Board.

8. Based upon the Accusation and the foregoing admissions, Respondents, and each of them, stipulate to the following penalties, which will become binding and enforceable upon approval of this Stipulation by the Board:

a. Board Staff and Respondents have not reached an agreement as to a penalty, if any, related to the First Cause of Action.

b. Lucas Meyer.: Related to the record keeping violations alleged in the Second Cause of Action, Mr. Meyer shall: (i) pay a fine of $500.00, and (ii) complete two one-hour CE units on the topics of pharmacy record keeping requirements (1 CE) and ethics (1 CE).

c. Tina Rizzolo, R.Ph.: Related to the violations alleged in the Third Cause of Action, Ms. Rizzolo shall: (i) pay a fine of $750.00, and (ii) complete two one-hour CE units on the topics of error prevention (1 CE) and elements of proper counseling (1 CE).

d. Walgreens #3922: Related to the Fourth Cause of Action, which relates back to the violations of Walgreens #3922's employees in the Second Cause of Action (Meyer - Record Keeping) and Third Cause of Action (Rizzolo - Counseling), Walgreens #3922 shall: (i), distribute a copy of the Accusation and Order(s) from this case, with the individual Respondents' names redacted, to all of its pharmacists who participate in filling prescriptions for Nevada residents, for their review and education as to pharmacists' responsibilities under Nevada law, and (ii) pay an administrative fee of $495.00.

e. Walgreens Mail Service: Related to the violations alleged in the Fifth Cause of Action, Walgreens Mail Service shall: (i) pay a fine of $1,000 for the violations of Ms. Wagner while working at its facility, and (ii) pay an administrative fee of $495.00.

9. The CE units agreed to above are in addition to the CE units each pharmacist is ordinarily required to complete to maintain a pharmacist license.

10. Board Counsel will present this Stipulation to the Board for approval at its meeting on January 13, 2016, in Las Vegas, Nevada. Respondents, and each of them, will appear at that meeting to answer questions put to them by members of the Board and Board Staff. The Board may discuss and deliberate regarding the Stipulation even if one or more Respondent is absent. The Board has discretion to approve this Stipulation, but it has no obligation to do so.

11. Except as to the allegations relating to the First Cause of Action, which remain unresolved, if the Board adopts the recommendations set forth above, Respondents and the Board each agree to release the other from any and all claims arising from the facts set forth in the Accusation, whether known or unknown, which might otherwise have existed on or before the effective date of the Board's Order in this matter.

12. If the Board rejects any part or all of this Stipulation, the parties agree that a full hearing on the merits of this matter may be heard by the Board, and that the hearing shall occur at the Board's April 13, 2016 meeting in Las Vegas, Nevada. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Respondents shall pay the *fines* agreed to herein by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 431 W. Plumb Lane, Reno, NV 89509, within 90 days of the effective date of the Board's Order.

14. Respondents shall pay the *administrative fees* agreed to herein by *cashier's check*, *certified check* or *money order* made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 431 W. Plumb Lane, Reno, NV 89509, within ninety (90) days of the effective date of the Board's Order.

15. Any failure by any Respondent to satisfy the obligations stated herein may result in additional discipline, up to and including suspension or revocation of each Respondent's respective registration/license, until all terms have been satisfied.

Signed this ___ day of January, 2016

S. PAUL EDWARDS, Esq.
General Counsel – Board of Pharmacy

Signed this ___ day of January, 2016

LUCAS MEYERS, RPH
Certificate of Registration No. 16064

Signed this ___ day of January, 2016

Tina Rizzolo, RPH
Certificate of Registration No. 17665

Signed this ___ day of January, 2016

WALGREENS PHARMACY
Certificate of Registration No. PHN01127

Signed this ___ day of January, 2016

WALGREENS MAIL SERVICE, INC.
Certificate of Registration No. PH01964

DECISION ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondents Tina Rizzolo, Certificate of Registration No. 17665, Lucas Meyers, Certificate of Registration No. 16064, Walgreens Pharmacy #3922, Certification of Registration No. PHN01127, and Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, respectively, and hereby orders that the terms of the foregoing Stipulation be made effective upon execution.

Signed this ___ day of January, 2016

Leo Basch, President
Nevada State Board of Pharmacy

Signed this 13 day of January, 2016

Tina Rizzolo, RPH
Certificate of Registration No. 17665

Signed this ___ day of January, 2016

WALGREENS PHARMACY
Certificate of Registration No. PHN01127

Signed this ___ day of January, 2016

WALGREENS MAIL SERVICE, INC.
Certificate of Registration No. PH01964

DECISION ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondents Tina Rizzolo, Certificate of Registration No. 17665, Lucas Meyers, Certificate of Registration No. 16064, Walgreens Pharmacy #3922, Certification of Registration No. PHN01127, and Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, respectively, and hereby orders that the terms of the foregoing Stipulation be made effective upon execution.

Signed this 13 day of January, 2016

Leo Basch, President
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TINA RIZZOLO, RPH** **Certificate of Registration No. 17665,** **LUCAS MEYERS, RPH** **Certificate of Registration No. 16064,** **WALGREENS PHARMACY #3922** **Certificate of Registration No. PHN01127, and** **WALGREENS MAIL SERVICE, INC.** **Certificate of Registration No. PH01964,** **Respondents.** /	**CASE NO. 15-028-RPH-A-S** **CASE NO. 15-028-RPH-B-S** **CASE NO. 15-028-PH-S** **CASE NO. 15-028-PH-O** **AMENDED FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, January 13, 2016, in Las Vegas, Nevada. S. Paul Edwards, Esq., represented the Board in his capacity as its General Counsel. William J. Stilling, Esq., of Parsons Behle & Latimer, filed an Answer and Notice of Defense and appeared at the hearing on behalf of Respondents Tina Rizzolo, RPh., Certificate of Registration No. 17665; Lucas Meyers, RPh., Certificate of Registration No. 16064; Walgreens Pharmacy #3922, Certificate of Registration No. PHN01127 (Walgreens Retail); and Walgreens Mail Service, Inc., Certificate of Registration No. PH01964 (Walgreens Mail Service).

Prior to the hearing, the Parties agreed to and entered into a written *Stipulated Facts*, a copy of which was filed and made part of the record in this action at the beginning of the hearing. Based on the Stipulated Facts, the Parties further entered into a *Stipulation and Order* resolving the Second, Third and Fifth Causes of Action in their entirety. The Stipulation and Order also partially resolved the Fourth Cause of Action as to Walgreen Retail's responsibility for Ms. Rizzolo's counselling error (Third Cause of Action).

With written stipulations in the record as to the facts and a majority of the causes of action, only two issues remained open for decision by the Board during the hearing:

(1) Whether a pharmacist who participates in a segmented prescription filling process is responsible for an error that a previous pharmacist in that process failed to detect and subsequently approved as accurate; and

(2) Whether a pharmacy that dispenses an incorrect medication under the circumstances described in issue one above is responsible for that dispensing error.

RELEVANT FACTS

Walgreens Mail Service is a Nevada-licensed mail service pharmacy located in Orlando, Florida. In May 2015, it was providing data verification support for Walgreens Retail located in Las Vegas, Nevada. Respondent Mr. Meyers worked for Walgreens Retail in Las Vegas at the time of the events alleged in the Accusation.

Those events began in May 2015, when a Nevada patient delivered to Walgreens Retail a prescription for thirty (30) Zoloft 200 mg. tablets with instructions to take 200 mg. by mouth daily. A pharmacy technician at Walgreens Retail performed data entry for the prescription and, rather than entering the medication prescribed, inadvertently entered Zocor 20 mg. tablets. The technician sent that erroneous prescription data into a data entry verification queue for pharmacist approval.

A pharmacist at Walgreens Mail Service in Florida, who was not licensed to practice pharmacy in Nevada, retrieved the data from the queue and verified it as accurate. That pharmacist did not detect the technician's error in entering Zocor, rather than Zoloft. The Florida pharmacist then put the prescription back into a queue for retrieval and filling by Walgreens Retail in Nevada.

Back in Nevada, another pharmaceutical technician retrieved the prescription information from the queue and filled the prescription with simvastatin (generic for Zocor). The technician staged the prescription for a pharmacist to conduct product verification. The verifying pharmacist, Respondent Mr. Meyers, purported to verify the product as accurate by comparing the label, the leaflet and the product in the prescription bottle to see that they matched. Mr. Meyers *did not review the original prescription or a*

copy of the prescription as part of the product verification process, and failed to detect that the prescription called for Zoloft, rather than the simvastatin he approved for dispensing. After completing product verification, Mr. Meyers placed the prescription bottle in Will Call for customer pickup.

Respondent Ms. Rizzolo, R.Ph., subsequently retrieved the prescription from Will Call and sold it to the patient. Neither she nor the patient detected the error.

ADDITIONAL FINDINGS

1. Mr. Meyers was the pharmacist on duty and had direct supervisory responsibility over the pharmaceutical technician who erred by entering Zocor rather than Zoloft as prescribed.

2. Mr. Meyers was the pharmacist on duty when the prescription returned to Walgreens Retail in Nevada and proceeded through the filling process.

3. Mr. Meyers performed product verification and personally failed to detect that the pharmacy was preparing to dispense the wrong medication.

4. The written prescription has a preprinted heading indicating that it was written by psychiatrist at a psychiatric practice.

5. Both the written prescription and a scanned copy of the prescription were available for Mr. Meyers to review at the time of product verification. Mr. Meyers did not review the prescription as part of the product verification process.

6. The foregoing findings are supported by the Answer(s) filed by the Respondents, the Stipulated Facts previously entered into the record, and testimony presented to the Board during the hearing.

CONCLUSIONS OF LAW

7. The Board has jurisdiction over this matter because, at the time of the conduct at issue, Respondent Mr. Meyers was a pharmacist licensed by the Board, and Respondent Walgreens Retail was a pharmacy licensed by the Board to operate in Nevada.

8. The Board is charged with protecting the health and safety of the public. NRS 639.070(1)(a). Pursuant to that charge, the Board has declared any "[failure to] strictly . . . follow the instructions of

[a] person writing, making or ordering a prescription or chart order as to its filling or refilling, the content of the label of the prescription or giving a copy of the prescription or chart order to any person...." to be "unprofessional conduct and conduct contrary to the public interest . . . ." NAC 639.945(1) (d).

9. The Board does not dictate a specific process that a pharmacy or its pharmacists must follow to comply with NAC 639.945(1) (d), nor does it prohibit pharmacies and pharmacists from segmenting the filling process such that it is completed by more than one pharmacist. However, where licensees opt to segment the filling process, they are still expected to develop and maintain policies and procedures that ensure that medication is dispensed correctly. A comparison of the original prescription, the label, the leaflet and the product to be dispensed would be a prudent element of that process.

10. Regardless of the process a pharmacy elects, if an error does occur, the Board's long-standing position has been to hold responsible, at a minimum, the pharmacist who made the error and the pharmacist who performed the product verification and approved the product for dispensing.

11. The Board's practice of holding pharmacies and pharmacists responsible for the actions of others is not foreign to Nevada pharmacy law. NRS 639.220, for example, states that a "managing pharmacist is responsible for the activities of [his or her] designee," where a staff pharmacist is left in charge of a pharmacy in the manager's absence.

Similarly, NAC 639.252 states that a "pharmacist supervising [a] pharmaceutical technician is responsible for the filled prescription," including verification of the "selection and strength of the drug . . . [t]he dosage form; and . . . [t]he labeling of the prescription." That is true, even where the pharmacist did not personally make the error. A pharmacist's responsibility over the actions of others in his or her charge is further set forth in NAC 639.702, which states:

> The owner of a pharmacy, the managing pharmacist of the pharmacy and the *registered pharmacist on duty at the pharmacy* are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission.

(Emphasis added.)

Moreover, NAC 639.268 makes a pharmacist responsible for the acts of any pharmaceutical technician under his/her supervision; NAC 639.945(2) makes a supervising pharmacist responsible for the acts of any intern pharmacist under his/her supervision; and NAC 639.467 states that "a staff pharmacist [in a medical facility] is responsible for any delegated act performed by pharmaceutical technicians under his or her supervision."

12. Consistent with those authorities and the Board's long-standing position that a final verifying pharmacist can be held responsible for approving an error, even if it was previously approved and passed along by other pharmacists in the filling process, the Board concludes here that Respondent Mr. Meyers violated NAC 639.945(1)(d) and (i) by unskillfully failing to strictly follow the instructions of patient A.P.'s physician and verifying as accurate simvastatin 20 mg. tablets, instead of the Zoloft 200 mg. tablets the patient's physician prescribed.

13. Mr. Meyers is responsible for that error on multiple levels. He was the pharmacist on duty and had direct supervisory responsibility over the pharmaceutical technician who erred during data entry.

14. Mr. Meyers, as the pharmacist on duty, is likewise responsible for the error of Walgreens Mail Service employee Ms. Wagner—who, due to her unlicensed status in Nevada, the Board deems to be "other personnel who are not pharmacists working in or for the pharmacy." Ms. Wagner failed to detect the technician's data entry error during data verification.

15. Mr. Meyers was still the pharmacist on duty when the prescription returned to Walgreens Retail in Nevada and proceeded through the filling process. Mr. Meyers performed product verification and *personally* failed to detect the error. He approved simvastatin, a medication indicated for high cholesterol, when the patient's physician prescribed Zoloft, a medication indicated for depression. In doing so, the Board concludes that Mr. Meyers failed to strictly follow the instructions of the patient's physician as alleged in the First Cause of Action.

16. Those violations are grounds for discipline pursuant to NRS 639.255.

17. During the hearing, Respondents argued that Mr. Meyers should not be held responsible due to the Board's findings and conclusions in *Nevada State Board of Pharmacy v. Doan et al.*, Case No.

14-076-RPH. The Board concludes that the *Doan* case is factually distinguishable from the instant matter. In *Doan*, the prescription required a prior authorization. The pharmacy prepared the authorization, but input the wrong medication and sent it to the prescriber for approval. The prescriber did not detect the error, authorized the fill, and returned the authorization, which the pharmacy scanned into its computer system as the prescription. Since the authorization indicated the wrong medication, the Board found that even if the pharmacist had reviewed the original document during product verification, that document contained no information that would have alerted the pharmacist to the error.

18. The facts in *Doan* are distinguishable from the facts here. Here, Walgreens Retail had the original prescription. It was available for Mr. Meyers to review. Looking at the prescription to verify that it matched the label, leaflet and product could have alerted Mr. Meyer to the error. In any event, the findings and conclusion in *Doan* are not necessarily binding on the Board here, and do not bar it from finding against Mr. Meyers in this action.

19. Based upon the forgoing finding of guilt, Mr. Meyers shall, related to the violations alleged in the First Cause of Action, (i) pay a fine of $250.00, and (ii) complete two one-hour CE units on the topics of pharmacy record keeping (1 CE) and proper error prevention techniques (1 CE).

20. During the hearing, the Board made no findings or conclusions regarding Walgreens Retail's responsibility for Mr. Meyer's error. The Board hereby dismisses the Fourth Cause of Action as to that issue only.

21. Each party is to bear its own costs and attorney fees.

22. The two (2) CEs ordered in the foregoing paragraph are in lieu of the two (2) addition CEs Mr. Meyer's agreed to in the Stipulation and Order, are in addition to the CEs Mr. Meyer is ordinarily required to complete for maintenance of licensure, and must be completed within ninety (90) days of entry of this order.

23. Respondents shall pay the <u>fines</u> set forth herein by cashier's or certified check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office within thirty (30) days of the effective date of this Order. If circumstances so merit, Board Staff

has the discretion and authority to establish a payment plan under which any of these Respondents may pay the fine(s) set forth herein through installments without further action or vote by the Board.

24. Respondents shall pay the administrative fees set forth herein by cashier's or certified check of money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office within thirty (30) days of the effective date of this Order.

25. Any failure by any Respondent to comply with any term in this Order may result in additional discipline, up to and including suspension or revocation of that respondent's registrations/licenses until all terms have been satisfied. Furthermore, any failure to pay any fine, fee, or cost ordered herein may result in such legal action as Board Staff determines to be necessary to collect the unpaid fine, fee, or cost.

26. This Amended Order supersedes the original order entered February 4, 2016.

IT IS SO ORDERED.

Signed and effective this 2 day of March, 2016.

Leo Basch, President
Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. TINA RIZZOLO, RPH Certificate of Registration No. 17665, LUCAS MEYERS, RPH Certificate of Registration No. 16064, WALGREENS PHARMACY #3922 Certificate of Registration No. PH01127, and WALGREENS MAIL SERVICE, INC. Certificate of Registration No. PH01964, Respondents.	Case Nos. 15-028-RPH-A-S 15-028-RPH-B-S 15-028-PH-S 15-028-PH-O **AMENDED APPLICATION AND REQUEST FOR REHEARING**

In accordance with NRS 639.252 and NRS 223B.130(4), Respondents, Lucas Meyers and Walgreens Pharmacy #3922, by and through William J. Stilling and Robert W. DeLong of and for Parsons Behle & Latimer, request a rehearing on the issues decided by the Amended Findings of Fact and Conclusions of Law and Order ("Findings and Conclusions") in the above-captioned matter based on the objections described herein. This Amended Application and Request for Rehearing replaces and supersedes the Application and Request for Rehearing, which incorrectly referred to the original Findings and Conclusions rather than the Amended Findings and Conclusions.

I. INTRODUCTION

The Board of Pharmacy's Findings and Conclusions constitute impermissible *ad hoc* rulemaking that go far beyond the question presented by the First Cause of Action. The Findings and Conclusions effectuated a policy by creating a standard of general applicability that essentially

bans workload balancing by eviscerating any benefit derived from having a different pharmacist verify data entry than the pharmacist who verifies the product. The Board also failed to rely on substantial evidence to find Mr. Meyers violated NAC 639.945(1)(d) and (i). Contrary to the rationale in the Findings and Conclusions, the Board reversed its long-standing position that a product verification pharmacist needs to look at the original prescription only under circumstances that would give the pharmacist a reason to believe there was an error. Rather than providing a reason for its policy change, the Board simply restated a contrary policy as if it were in fact true.

II. OBJECTIONS TO FINDINGS OF FACT AND CONCLUSIONS OF LAW AND ORDER

A. Respondents Object to the Following Sections of the Introductory Comments.

1. Paragraphs (1) and (2) of the Introduction Purport to Decide a Question Different from and Broader than the Question before the Board and Constitute Impermissible *ad hoc* Rulemaking.

An agency can only decide the matter before it. It cannot use a single adjudication to create a standard of general applicability to effectuate a policy. The two questions in paragraphs (1) and (2) go far beyond the questions before the Board of Pharmacy and created a directive of general applicability that effects how Walgreens conducts business and how all other pharmacies in Nevada must conduct business. Paragraphs (1) and (1) expanded the questions before the Board to include circumstances and issues that were not presented in the Notice and Accusation and that were not necessary for the Board to render a decision.

> With written stipulations in the record as to the facts and a majority of the causes of action, only two issues remained open for decision by the Board during the hearing: Those two questions are:
>
> (1) Whether a pharmacist who participates in a segmented prescription filling process is responsible for an error that a previous pharmacist in that process failed to detect and subsequently approved as accurate; and

> (2) Whether a pharmacy that dispenses an incorrect medication under the circumstances described in issue one above is responsible for that dispensing error.

See Findings and Conclusions at p. 2.

Only the First Cause of Action remained for the Board to decide at the January 13, 2016 hearing and these two paragraphs far exceed the scope of the issue the First Cause of Action presented. The First Cause of Action alleged the following:

> In failing to strictly follow the instructions of A.P.'s physician by verifying and dispensing a prescription for *simvastatin 20 mg. tablets (generic Zocor),* rather than the *Zoloft 200 mg. tablets* the patient's doctor prescribed, Mr. Meyers violated NAC 639.945(1)(d) and/or (i), which violations are grounds for action pursuant to NRS 639.210(4), (I I), and/or (12), and NRS 639.255.

Thus, the sole question the Board had to answer was *whether under the facts and circumstances contained in the Stipulated Facts,* did Mr. Meyers violate the statutes listed in the First Cause of Action. The Board has authority to determine whether Mr. Meyers violated statutes and rules described in the Notice and Accusation based on the facts alleged, or in this case on the Stipulated Facts. It cannot decide generally whether "a pharmacist" (i.e., any pharmacist) who participates in "a segmented filling process" (i.e., any segmented process including retail pharmacies doing so in the same pharmacy, hospital pharmacies, and all other pharmacies) is responsible for an error that "a previous pharmacist" (i.e., any pharmacist in any segmented process in any pharmacy) failed to detect and subsequently approves as accurate.

Even worse, the Board's broad decision announced a general policy that essentially banned workload balancing, a process that allows one pharmacy to relieve a heavy workload at another pharmacy by completing the verification process when the first pharmacy is overwhelmed with work. If the pharmacist who is under a heavy workload and is being relieved must go back and check everything the other pharmacy checked, there is no point in workload balancing, which

Board members and industry recognize as a helpful, safe process.[1] By making a broad conclusion about the responsibilities of all pharmacies and pharmacists who participate in a segmented filling process and who did not have an opportunity to be heard, the Board engaged in prohibited *ad hoc* rule making. *See Coury v. Whittlesea-Bell Luxury Limousine*, 721 P.2d 375 (Nev. 1986); *Texas State Board of Pharmacy v. Witcher*, 447 S.W. 3d 520 (Tex. Ct. App. 2014) (board could not sanction pharmacist with informal policy that amounted to "ad hoc" rulemaking).

In *Coury*, the Public Service Commission determined the limits of what constitutes a stretch limousine. Thus, "by commission fiat," the agency set "a standard of general applicability which effectuates commission policy." The Nevada Supreme Court agreed the "commission had set, 'ad hoc,' (*i.e.*, without the formal requisites for promulgation of regulations provided for in NRS 233B) a new standard for limousines, namely, a 'stretch' limousine. It is difficult, on this record, to claim that this new standard was not of general applicability, or does not set policy for the future." *Coury* at 377.

Likewise in this case, the Board set a standard of general applicability when it destroyed any benefit workload balancing has to alleviate a pharmacy overwhelmed by a rush or prescriptions (i.e., having a pharmacist verify data entry and thereby taking the load off a pharmacist checking that the product is correct). The Board answered questions about how all pharmacies and pharmacists must operate their practices rather than answering the discrete question about whether

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[1] At a D&D held on March 2, 2016, Board members agreed that requiring a product review harmacist to review all the data might actually be less safe. Commenting on the requirement for a second pharmacist to check the work of the first pharmacists, one Board member said: "That kind of defeats the whole point of workload balancing [if] everybody is going to verify everything that everybody has done before. That seems to me to put more work on the last verifier." Another Board member commented on the workload balancing by an out-of-state call center and agreed it helps pharmacists prevent mistakes: "I think that that model is good because you have fewer distractions in a call center environment and, like you said, you can change the, you do the changes in workload, very efficiently. And so I just want you to know that I'm not saying that shouldn't be part of the process personally. I that that's good personally. As a pharmacist I say it's good. It's certainly helped a lot of pharmacists get the work done, the work in front of them." *See* Recording of D&D on March 2 at 28:14 and 32:02 respectively.

Mr. Meyers was liable when a pharmacist in Florida failed to detect the error of a technician. Therefore, the Board impermissibly engaged in *ad hoc* rulemaking by issuing "a directive or statement of general applicability, which effectuates or interprets law or policy" without undertaking the rulemaking process. *See* NRS 223B.038 and the Nevada Administrate Procedures Act governing administrative regulations at NRS 233B.0395 – 223B.120.

B. RESPONDENTS OBJECT TO THE FOLLOWING FACTS LISTED UNDER RELEVANT FACTS.

1. The Statement that the Patient Delivered a Prescription for "thirty (30) Zoloft 200 mg. tablets" Does Not Match the Prescription Order.

The second paragraph references a prescription for "thirty (30) Zoloft 200 mg. tablets." This is consistent with the Stipulated Facts signed by counsel for all parties. However, Zoloft is not available in 200 mg tablets. Rather, the Stipulated Facts and the Findings and Order should read as "Zoloft 200 mg by mouth daily—No. 30."

C. RESPONDENTS OBJECT TO THE FOLLOWING PARAGRAPHS IN THE CONCLUSIONS OF LAW.

1. Paragraph 9

a. The Board Engaged in ad hoc Rulemaking.

The Board correctly stated it "does not [or should not] dictate a specific process that a pharmacy or its pharmacists must follow." Indeed, by doing so, the Board would engage in *ad hoc* rulemaking, which is described in section II.A.1. above. Contrary to this correctly stated principle, the Board eviscerated the ability of pharmacies to perform workload balancing and dictated a specific process for every pharmacy licensed in Nevada without any opportunity for any affected pharmacist or pharmacy to be heard. No pharmacist who reads the Board's Findings will feel legally able to rely on another pharmacist's data verification when workload balancing attempts to alleviate the stress on the pharmacist. After the Board's decision, all pharmacies in

Nevada engaged in segmented prescription filling or work load balancing must implement a specific process in which each pharmacist must check the work of the pharmacist who verified the data entry or risk being guilty for violating NAC 639.945(1)(d) and (i).

b. The Board Failed to Rely on Substantial Evidence.

The Board concluded that Mr. Meyers Violated NAC 639.945(1)(d) and (i) (respectively, failing to strictly follow the instructions of the person writing the prescription and acting "in an incompetent, unskillful, or negligent manner"). Section 639.945 is a generally worded rule that must be interpreted on a case-by-case basis. Whether a pharmacist acts incompetently, unskillfully, or negligently is a question of whether the pharmacist met the standard of practice for a reasonable and prudent pharmacist. Thus, the Board must present substantial evidence that a pharmacist violated section 639.945. The Nevada Supreme Court affirmed this principle in *Nevada State Board of Pharmacy v. Garrigus*, 496 P.2d 748 (Nev. 1972). In *Garrigus*, the court affirmed the district court's dismissal of the Board's decision because "there was no evidence or testimony produced that established what the standard was that constituted conduct that became unprofessional if breached." The Board revoked two pharmacists' licenses because they dispensed an inordinate amount of Numorphan (9,250 tablets and 580 syringes over a four-month period). The court explained, "[t]here is no evidence in the record that the amount of drugs sold to Chapman was excessive under the circumstances, no proof was elicited as to what does or does not constitute unprofessional conduct in the pharmacy business, and no evidence was presented as to what were the contemporary standards in the profession." *Id.* at 749. In the present case, there was no evidence that Mr. Meyers acted incompetently, negligently, or unskillfully. Rather, the Board impermissibly drew its own conclusions without any supporting evidence about the standard of industry practice. "The fact that the respected members of the board felt respondents' conduct improper is not enough to provide their hearing with requisite due process." *Id.* at 749. If the

Board in this case wants to find Mr. Meyers guilty for unskillful, incompetent, or negligent conduct, it must present substantial evidence on rehearing to prove a violation of NAC 639.945(1)(d) and (i). Otherwise, the Board's conclusion must be vacated.

As to the Board's conclusion that Mr. Meyers failed to strictly follow the instructions of the person writing the prescription under NAC 639.945(1)(d), the Board ignored the fact that another pharmacist checked the prescription to ensure it strictly followed the prescriber's instructions. There is no Nevada law or rule that requires a pharmacist to check the accuracy of another pharmacist's work. Thus, Mr. Meyers strictly followed the instructions as they were presented to him.

In Walgreens' process, like most modern pharmacies, the prescription filling process is segmented to optimize safety so pharmacists focus on specific information to insure its correctness. Therefore, a pharmacist ("Pharmacists 1" or "P1") conducts data verification by focusing on each field (e.g., drug, dose, instructions) the technician entered into the computer from the hard copy prescription. Pharmacist 1 must pass several "hard stops" to make sure each field is correct. The label and patient information leaflet are generated by Pharmacist 1's review. The product verification pharmacist ("Pharmacist 2" or "P2") is supposed to focus on the product and labels to ensure the technician used the correct medication, based on the Pharmacist 1's verification, and that the right medication is in the container for the correct patient.

Thus, P1 checks the accuracy of the entered data and is responsible for ensuring the prescriber's instructions are strictly followed. There is nothing in the laws or rules that requires another pharmacist to check the original data for every prescription. Yet, that is exactly what the Board ruled—that in a segmented filling process, the pharmacist who is supposed to focus on the product and labels, must divert that focus to check the first pharmacist's entry.

The Board seems to believe that because a mistake made it through this process, the process is unsafe and that all pharmacies and all pharmacists in Nevada (not just Mr. Meyer, not just this pharmacy, not just Walgreens' pharmacies) must change the specific process by which they fill prescriptions. Yet, the Board presented no evidence that the new process the Board requires is any safer. In fact, requiring the product verification pharmacist to undertake another function is likely to result in more errors of a different type—wrong products being dispensed even when the information verified by the first pharmacist is correct.[2] Without evidence as to the safety of one process over another, the Board had no evidence upon which to reach its conclusion.

2. Paragraph 10

a. The Decision is Contrary to the Board's Longstanding Policy about when P2 Must Review the Original Prescription.

The record does not support the conclusion that "if an error does occur, the Board's longstanding position has been to hold responsible, at a minimum, the pharmacist who made the error and the pharmacist who performed the product verification and approved the product for dispensing." Instead, the longstanding position of the Board is that P2 must review the original prescription when circumstances give P2 a reason to suspect something is amiss. The cases referenced by Board counsel reiterate this long-standing position, not the new, contrary position the Board turned to in this case.

The Board spent time discussing *Nevada State Board of Pharmacy v. Doan, et al,* a case it decided in 2015. In *Doan,* described in paragraphs 17 and 18 of the Conclusions of Law, the Board specifically concluded the product checking pharmacist was not responsible for the error of the data entry pharmacist (i.e., P2 was not responsible for the error of P1). In *Doan*, the Third Cause

[2] See comments in footnote 1.

of Action against the product verification pharmacist was the same as in this case. After hearing testimony about the segmented process, the Board concluded:

> Although evidence exists to support the primary factual allegation underlying the Third Cause of Action—specifically that Respondent Ms. Blair did not detect the dosage error during product verification—the Board concludes that Ms. Blair did not violate the law.

See Doan, Findings of Fact, Conclusions of Law and Order ¶ 12.

Contrary to the attempts in the Findings and Conclusions to distinguish Doan from this case, the Board's discussion in *Doan* reflects the fact that each error must be judged in the circumstances of the case. Just before he made his motion to dismiss the Third Cause of Action, in *Doan,* Board Member Jason Penrod explained:

> So if we take a look at the other pharmacies, or even some of the, some of our independents, when you take a prescription like this, it's, it's passing through the system as the hard copy. They don't have the benefit of seeing that prescription on the screen, and so, in a case like this where the prescription was originally checked and placed on hold, that prescription is then filed. We're talking about something that happened a week later. This may actually already be in, in the file boxes, in the storage in the pharmacy. That aside, we in some ways, it's almost like we're penalizing those pharmacies that have chosen to update their systems, which arguably, in many ways, increase patient safety. So, it, we, we wouldn't necessarily be able to hold that pharmacist accountable at that store where the prescription is filed because they'll never have that opportunity, short of going and digging for that prescription to see it after it's been on hold in a case like this.
>
> . . . .
>
> If you've chosen to stick with the old operating system, which in some ways it can be more of a safety issue than the newer more advanced systems, are we going to ultimately give them a pass when they, when they come before the board. Because I don't see how we can find against the pharmacists working in that environment. . .
>
> .

> So, *the case of Ms. Blair, she has a prescription for a patient who she is familiar with and knows that this patient, and is in the type of care that she is, and the dose is, is more than appropriate.* And ultimately she's following SOP, so do we as a board help facilitate patient safety and the job of that pharmacist in the, in the product verification process and request that Walgreens provide that, that, that image to the pharmacist in the product verification process, and allow them to have the discretion whether or not they choose to, to utilize that resource? But ultimately, I have a hard time finding fault in Miss Blair.

See Recording of *Doan, et al* (Walgreens 14-076-N-3) at approximately 22:00. The Board's decision in *Doan* hinged on the fact that there was nothing about the dosage in that case to give the product check pharmacist a reason to go back to look at the original prescription.[3] As Mr. Penrod said, the prescription information that came to the product check pharmacist was a "prescription for a patient who she is familiar with and knows that this patient, and is in the type of care that she is, and the dose is, is more than appropriate."

In the quoted text above and in another question during his motion to find the pharmacist not guilty, Mr. Penrod questioned whether the Board could make Walgreens change its computer system to require the original image to appear. Dave Wuest, Deputy Executive Secretary for the Board, appropriately recognized that this was an issue for discussion at a later Board meeting when the Board could obtain further input about various prescription filling and verification processes. He explained:

> Well I think that what's appropriate is we'll have a discussion with Walgreens like we always do. And *it may be something that we want to do some discussion and determination [D&D],* I talk with Leo about that as we took our break. So I think we can handle on that. I think focus on what the case is today, find, or not to dismiss, but to find not guilty. And then we'll just move forward.

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[3] Respondents encourage Board staff reviewing this Application and Request to listen to the whole recording to verify Respondents' position. Such a review will reveal there is nothing in the record to indicate P2 in the *Doan* case would not have discovered the dosing error if she had pulled up the original prescription.

Id.

b. Cases Referenced (indirectly) during the Hearing Are Contrary to the Longstanding Policy Asserted in Paragraph 10.

During the hearing, Board counsel claimed that the Board had waffled on the issue of whether a product-checking pharmacist would be liable for the mistakes of a data verification pharmacist. Counsel explained he had looked up cases, though he did not cite them directly at the hearing. Upon request of Respondents' counsel several weeks after the hearing, Board counsel provided those cases to Respondents' counsel. In the first case, *Nevada BOP v. Goff, et al*, Case 06-069, the Board held the pharmacist responsible for failing to check another pharmacist's work when there were reasons to believe there was something wrong with a TPN. Despite following the pharmacy's protocol, the pharmacist had reason to suspect an error when the drug order and TPN were presented. These included: (i) the poor reputation of the technician; (ii) the volume of the IV bag was larger than pediatric IVs; and (iii) the order he used to check the manual additives stated that there was 481 ml of zinc in an IV with a total volume of 580 ml. This is a case where the Board concluded the pharmacist had a responsibility to check further because multiple red flags alerted the pharmacist something was amiss.

In *Nevada BOP v. Walgreens #2474, Mann, et al,* the Board held the product verification pharmacist responsible for dispensing clomipramine instead of clomiphene. The basis for the finding was not simply that the product verification pharmacist must check the data verification pharmacist's work. Rather, the same pharmacist who performed the product review also received the telephone prescription for clomiphene 50 mg tablets and transcribed it. Thus, the pharmacist had reason to suspect the wrong drug when it was presented to him for a product check.

In the final case, *Nevada Board of Pharmacy v. Martins, et al*, 06-023, the pharmacist filled a prescription for a dose of Reglan that was too large for a child. The Board found the pharmacist,

Martins, guilty because he received the prescription from the father, verified the data, and dispensed the prescription. As in the other cases, the Board found the pharmacist responsible because he had reason to go back and check the prescription. The pharmacist: (i) knew the patient was a child; (ii) knew the dose was large; (iii) knew the syringe was too small for the 7 mg dose; and (iv) appeared to have lied to the mother about having the prescription in front of him, which served as a type of admission that the prescription held the answer to the mother's questions. Again, the Board followed the longstanding rule that a pharmacist is guilty under NAC 639.945(1)(d) and (i) for not looking at the original prescription when the circumstances should alert the pharmacist that something is wrong. There was no general pronouncement that pharmacists must always check the work of the pharmacist who previously verified information.

Over and over again, the Board has ruled that a pharmacist verifying that the product is correct is not required to go back and look at the original prescription or order unless circumstances raise red flags that something is wrong with the prescription. While an agency need not follow each prior case as if such cases are immutable *stare decisis*, an agency cannot simply disregard policy established by its prior decisions. To do so would constitute arbitrary and capricious decision making and would undercut the integrity of the agency. Thus, while not strictly bound to a string of prior consistent rulings, an agency is required to explain its reasoning for departing from such earlier decisions. *See Texas State Board of Pharmacy v. Witcher,* 447 S.W. 3d 520, 534 (Tex. Ct. App. 2014); *Pickett v. Utah Department of Commerce,* 858 P.2d 287 (Utah App. 1993) (pharmacist's controlled substances license was revoked and court remanded for less severe penalty because agency failed to provide an explanation why the penalty imposed is not aberrational when compared with other decisions, the court). The Board failed to provide any

rational for departing from its longstanding policy that product checking pharmacists need to check the original prescription when circumstances raise a concern of danger.

3. Paragraph 11

In paragraph 11, the Board used NRS 639.220, NAC 639.252, NAC 639.702, NAC 639.268, NAC 639.945(2), and NAC 639.467 as bases for its decision. Yet, the Notice and Accusations did not contain reference to any of those laws or rules. The Nevada Administrative Procedures Act specifically requires that the notice of a hearing in a contested case must contain a "reference to the particular sections of the statutes and regulations involved." NRS 233B.121(2)(c). This assures that an agency must meet the fundamental requirements for due process–meaningful notice and opportunity to be heard under the Fourteenth Amendment of the United States Constitution and Section 8(5) of the Nevada Constitution. Using these sections as bases for the decision without including them in the Notice and Accusation violates NRS 233B.121(2)(c) and Respondents' due process rights. *See e.g., Coury v. Whittlesea-Bell Luxury Limousine,* 721 P.2d 375, 378 n.2 (Nev. 1996).

4. Paragraph 12

Respondents object to paragraph 12 because it is based on laws and regulations that were not in the Notice and Accusation and the Board did not provide substantial evidence to demonstrate its claim. Respondents incorporate and reassert the basis and reasoning for the objections in Sections II.A.1. and C.1-3 above as applied to the findings in paragraph 12.

5. Paragraph 13

Respondents object to paragraph 13 because it claims Mr. Meyers is responsible for supervising the pharmacist who was working under the license of the license of the Nevada-licensed Mail Order Pharmacy, yet that claim is based on laws and regulations that were not in the Notice and Accusation and the Board did not provide substantial evidence to prove its claim.

Respondents incorporate and reassert the basis and reasoning for the objections in Sections II.A.1. and C.1-3 above as applied to the findings in paragraph 13.

6. Paragraph 14

Respondents object to paragraph 14 because it claims Mr. Meyers is responsible for supervising the pharmacist who was working under the license of the license of the Nevada-licensed Mail Order Pharmacy, yet that claim is based on laws and regulations that were not in the Notice and Accusation and the Board did not provide substantial evidence to demonstrate its claim. Respondents incorporate and reassert the basis and reasoning for the objections in Sections II.A.1. and C. -3 above as applied to the findings in paragraph 14.

7. Paragraph 15

Respondents object to paragraph 15 because it fails to cite a law or regulation and because it is not based on substantial evidence. Respondents incorporate and reassert the basis and reasoning for the objections in Sections II.A.1. and C.1-3 above as applied to the findings in paragraph 15.

8. Paragraph 16

Respondents object to paragraph 16 because the bases for unprofessional conduct under NRS 639.255 are all the other paragraphs in the Findings and Conclusion to which Respondents object. Respondents incorporate and reassert the basis and reasoning for the objections in Sections II.A.1. and C.1-3 above as applied to the findings in paragraph 16.

9. Paragraph 17

Respondents object to paragraph 17. The reasons for the objection is embedded in the explanation of the objection for paragraph 12 and as set for in the discussion of the *Doan* case in paragraph II.C.2. above. Respondents incorporate and reassert the basis and reasoning for the objections in Sections II.A.1. and C.1-3 above as applied to the findings in paragraph 17.

10. Paragraph 18

Respondents object to paragraph 18 and incorporate by reference paragraph II.C. 9 above. Respondent objects because there was no basis for the findings of violations and therefore no basis for sanctions.

11. Paragraph 19

Respondents object to paragraph 19 because there is no basis for the sanctions as described in the foregoing sections. Respondents incorporate and reassert the basis and reasoning for the objections in Sections II.A.1. and C. 1-3 above as applied to the findings in paragraph 19.

12. Paragraph 22-25

Respondents object to paragraphs 22-25 because there is no basis for the sanctions as described in the foregoing sections. Respondents incorporate and reassert the basis and reasoning for the objections in Sections II.A.1. and C. 1-3 above as applied to the findings in paragraphs 22-25.

DATED this 16th day of March, 2016.

William J. Stilling
of and for PARSONS BEHLE & LATIMER
Attorneys for Respondents
Lucas Meyers, Walgreens Pharmacy #3922,
and Walgreens Mail Service, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on March 16, 2016, I caused to be served a true and correct copy of the foregoing **AMENDED APPLICATION AND REQUEST FOR REHEARING** by the method indicated below to:

Larry Pinson
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S. Paul Edwards
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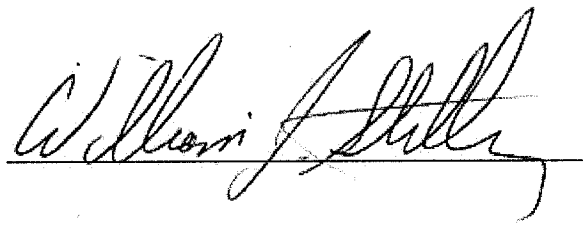
- ☐ U.S. Mail postage prepaid
- ☐ Hand delivery
- ☐ Overnight Mail
- ☐ Facsimile
- ☑ Electronic Mail



BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TINA RIZZOLO, RPH** **Certificate of Registration No. 17665,** **LUCAS MEYERS, RPH** **Certificate of Registration No. 16064,** **WALGREENS PHARMACY #3922** **Certificate of Registration No. PHN01127, and** **WALGREENS MAIL SERVICE, INC.** **Certificate of Registration No. PH01964,** **Respondents.** /	**CASE NO. 15-028-RPH-A-S** **CASE NO. 15-028-RPH-B-S** **CASE NO. 15-028-PH-S** **CASE NO. 15-028-PH-O** **RESPONSE TO AMENDED APPLICATION AND REQUEST FOR REHEARING**

INTRODUCTION

There is no reason for the Board to withdraw or further amend its *Amended Findings of Fact and Conclusions of Law* ("Findings and Conclusions") in this matter. The Board correctly applied existing law to conclude that Respondent Lucas Meyers ("Meyers") is partially responsible for dispensing the wrong medication to patient A.P. Fortunately, A.P. discovered the error after ingesting only one tablet. He suffered no harm, but similar cases have shown that dispensing errors can cause serious patient injury.

Respondents Meyers and Walgreens Pharmacy #3922 (collectively "Walgreens") now seek to deny Meyers's responsibility. In its *Amended Application and Request for Rehearing* ("Application"), Walgreens incorrectly argues that the Board engaged in "*ad hoc* rulemaking," or in other words, that the Board did not apply properly adopted regulations. Ironically, Walgreens then urges the Board to disregard its adopted regulations and reach a conclusion that has no regulatory support. The Board should reject that argument.

Additionally, Walgreens argues incorrectly that there is no clear standard by which Meyers's conduct may be measured. It claims that before the Board could find that Meyers acted in an

incompetent, unskillful or negligent manner, Board Counsel must present substantial evidence at a hearing to establish that Meyers had a duty to act in a particular way. That argument fails. The regulations the Board cited in its Findings and Conclusions establish a clear standard by which Meyers's conduct can be measured. The Board measured Meyers's conduct with those standards and found it inadequate. He did not fulfill his regulatory responsibilities, and the Board held him accountable.

Finally, Walgreens argues that the Board violated his right to notice and due process by failing to cite in the Accusation each of the regulations it applied in the Findings and Conclusions. That argument fails in light of NRS 639.241, which requires the Board to cite only the statutes and regulations Meyers was accused of violating. The Accusation clearly satisfies that standard.

Each of those issues are addressed in greater detail below. None of Walgreens's arguments have merit, and the Board should affirm its Findings and Conclusions.

DISCUSSION

A. The Board Correctly Applied Existing Statutes and Regulations and Concluded that Meyers Is Responsible for Dispensing the Wrong Medication to a Patient.

The Board did not engage in *ad hoc* rulemaking here. *Ad hoc* rulemaking occurs where an agency promulgates a new rule without adhering to the formal rulemaking requirements of the Nevada Administrative Procedures Act.[1] Instead, the Board reached its Findings and Conclusions by applying existing Nevada regulations, which apply generally to all Nevada-licensed pharmacists, including Meyers.

The regulations the Board applied include NAC 639.252(2), which the Board adopted in 1993. The regulation says that where a technician helps in the filling process, a "pharmacist supervising [the] pharmaceutical technician is responsible for the filled prescription . . . ." The regulation goes on to say specifically that the supervising pharmacist is responsible for the "*selection* and strength *of the drug* . . . [t]he dosage form; and . . . [t]he *labeling of the prescription.*" (Emphasis added.)

Applying NAC 639.252(2), the Board concluded that Meyers is responsible for technician Noelle Mallari's (Mallari) errors because he was the pharmacist supervising her when she selected the wrong medication to dispense to A.P. Meyers could fulfill his responsibility for Mallari's work only by

[1] NRS 233B.039 through NRS 233B.120

verifying the drug she selected and the information on the label against the original prescription. Meyers testified at the hearing that he did not look at the copy of the prescription available to him. His decision to disregard the prescription does not excuse him from his responsibilities under NAC 639.252. Thus, Meyers was responsible, at least in part, for failing to follow the instructions of A.P.'s physician and dispensing the wrong medication.

Similarly, the Board applied NAC 639.702, another regulation added in 1993, to bolster its conclusion that Meyers is responsible for the dispensing error in this case. That regulation says that a "pharmacist on duty at the pharmacy [is] responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy. . . ." That regulation further supports the conclusion that Meyers was responsible for Mallari's error in selecting the wrong medication, just as it supports the conclusion that he was responsible, at least partially, for non-Nevada pharmacist Ellen Wagner's failure to detect Mallari's error while working in Florida, and technician Courtney Watkin's error in putting the wrong medication in the bottle. Further, Meyers *personally* failed to detect the data entry error during verification. Thus, the Board correctly determined that Meyers, as the only Nevada-licensed pharmacist to see the prescription up through verification, is, at least partially, responsible for dispensing the wrong medication to A.P.

While it is clear that the Board did not previously engage in *ad hoc* rulemaking, Walgreens ironically seems to invite it to engage in *ad hoc* rulemaking here by asking it to disregard its regulations and excuse Meyers from his regulatory responsibilities. Nothing in the law says that a pharmacist's regulatory responsibilities are excused by the injection of another pharmacist into the filling process. Likewise, nothing in the law allows a pharmacy to unilaterally excuse its pharmacists from their responsibilities under NAC Chapter 639 just because it adopts a workload sharing model. The Board should reject that invitation and continue to apply its existing regulations. It should hold Meyers to the regulatory responsibilities placed on him and affirm the discipline it imposed because Meyers played an integral role in dispensing the wrong medication to A.P.

B. Substantial Evidence Supports the Finding that Meyers Acted in An Incompetent, Unskillful or Negligent Manner.

Substantial evidence supports the Board's finding that Meyers violated NAC 639.945. Walgreens complains that there is no clear standard by which Meyers's conduct can be measured. It suggests that Board Counsel must present additional evidence at a hearing to establish a standard for judging Meyers's conduct. That is not correct. The standards for measuring Meyers's conduct and all similarly situated Nevada pharmacists are already set by regulation. No additional evidence is needed to show their existence.

One standard Meyers violated is found at NAC 639.945(1)(d). A pharmacist must follow a prescriber's instructions and dispense only what was prescribed. *See* NAC 639.945(1)(d). Dispensing the wrong medication, or failing to follow the prescriber's instructions, is "unprofessional conduct and conduct [that is] contrary to the public interest." *Id.* The regulations articulate the standard of practice that all reasonable and prudent pharmacists must follow, including Meyers.

Meyers violated that standard when he dispensed Zocor 20 mg. tablets to patient A.P., despite the doctor's instructions to dispense Zoloft 200 mg. tablets. There is substantial evidence in the record to support that finding, particularly since Meyers and Walgreens, through their counsel, stipulated to that error in the Stipulated Facts at paragraph 3. Meyers violated that standard both personally, and as the supervisor of the technician and pharmacy employees who contributed to that error, as discussed in Section A above.

Other standards the Board used to measure Meyers's conduct are found in the Board's existing regulations. Under NAC 639.945(i), for example, Meyers acted unprofessionally and contrary to public interest when he performed his duties in an "incompetent, unskillful or negligent manner." As technician Mallari's supervising pharmacist, Meyers had the duty to verify that Mallari selected the correct drug to put in the bottle and to be printed on the prescription label. *See* NAC 639.252(2). Meyers testified during the hearing that he did not fulfill that responsibility because he did not look at the scanned copy of the prescription that was available to him to verify that Mallari selected the correct medication. He had similar supervisory duties under NAC 639.252(2) and NAC 639.702 over technician Watkins, who filled

the prescription bottle and staged it for verification, and the pharmacy's non-Nevada licensed employees. The evidence is that he breached those duties by failing to detect at verification that Florida-pharmacist Wagner missed Mallari's data entry error, and that Watkins put the wrong medication in the bottle. Board Staff did not charge Meyers for breaching each of those specific duties, but it did charge him with violating NAC 639.945(i). He did in fact violate that statute because he participated in failing to follow the instructions of A.P.'s physician.

Walgreens cites *Nevada State Board of Pharmacy v. Garrigus* for the proposition that Board Counsel needs to offer evidence at the hearing to establish Meyers's duties before the Board could determine whether he breached them. *See* Amended Application, p.6 (*citing* 88 Nev. 277, 496 P.2d 748 (1972)). That is nonsense. *Garrigus* is clearly distinguishable. In that case, the question was whether two pharmacists had dispensed excessive amounts of the drug Numorphan. The Nevada Supreme Court dismissed the Board's case against those pharmacists because there was no statute or regulation that dictated what constituted an excessive amount of Numorphan. In the absence of such a standard, the Court concluded that it needed evidence to establish the standard, and the Court dismissed the case because the prosecution entered no such evidence. That is not the case here. Here, existing regulations establish pharmacists' duties regarding supervising pharmacy technicians and staff, as well as pharmacists' responsibilities over technicians' and staff's errors and omissions. No external evidence is needed or appropriate because the regulations provide the standard and instruct all pharmacists, including Meyers, as to how they must act under the circumstances presented here. *Garrigus* is therefore distinguishable from this case. It does not support Walgreens's argument.

Similarly, Walgreens complains that there is no Nevada law or rule that requires a pharmacist to check the accuracy of another pharmacist's work. Pg. 7, ¶2. That is not the question here. The question is whether Meyers is responsible for dispensing the wrong medication to A.P. NAC 639.495(d) and (i) both say that it is unlawful to dispense the wrong medication to a patient, and the regulations cited above show that Meyers is at least partially responsible for that dispensing error. Walgreens's adoption of a

segmented filling process that deprives or discourages Meyers from fulfilling his duties does not excuse him from those responsibilities.

C. This Case is Not a Significant Departure from the Board's Prior Precedent.

Walgreens argues that the Board's Findings and Conclusions in this case are somehow a departure from Board precedent in other cases. Citing *Nevada BOP v. Goff, et al*, Case No. 06-069; *Nevada BOP v. Walgreens #2474, Mann, et al*, Case No. 13-070 and *Nevada Board of Pharmacy v. Martins, et al*, 06-023, Walgreens announces a rule that the Board should hold verifying pharmacists responsible for dispensing errors only where the circumstances of the case should have prompted further investigation. Applying that rule (without conceding that it really is the rule), this case is a case where the circumstances should have prompted Meyers to look further. At a minimum, it behooved Meyers to look at a copy of the prescription during verification. Meyers, not the pharmacist in Florida, bore the responsibility over technician Mallari's work. NAC 639.252(2). He was responsible to verify, among other things, the drug Mallari *selected*, and the *information on the label*. He was also responsible for the actions of technician Watkins, who staged the prescription for verification. *Id.* He could not possibly have verified either technician's work and meaningfully taken responsibility for their actions without, at a minimum, looking at a copy of the prescription.

Similarly, Walgreens argues that "[t]here is nothing in the laws or rules that requires another pharmacist to check the original data for every prescription." Amended Application, p.7, ¶4. That is not what the Board held. NAC 639.245(3)(c) does say, however, that a technician may not dispense a prescription unless the prescription has been verified by a *pharmacist*. Pharmacist, under Nevada law, means a pharmacist registered in the State of Nevada. NRS 639.015; *see also* NRS 453.371. At the time that the prescription at issue here arrived at Meyers's counter for approval, he was the first Nevada-registered pharmacist to see it. Presumably, if the A.P. had arrived to purchase his medication while Meyers was on duty, Meyers could have been the only Nevada-registered pharmacist to see it. Under circumstances where Meyers was the first Nevada-licensed pharmacist to see the prescription, and where he was potentially the only Nevada-licensed pharmacist to touch the prescription after it was processed by

two technicians and a non-Nevada licensed pharmacist, Meyers had reason to look at the prescription as part of the verification process. His actions do not satisfy the rule Walgreens attempts to announce.

D. The Accusation Cited Every Regulation the Board Concluded that Meyers Violated.

The Board did not violate Meyers's right to notice or due process. NRS 639.241—the statute that dictates what must go into a *Board of Pharmacy* Accusation—requires that an "accusation must specify the statutes and regulations which the respondent is alleged to have violated." The accusation in this action cites NAC 639.945(1)(d) and (i), which are the only two regulations the Board concluded that Mr. Meyers violated. The Accusation therefore satisfies NRS 639.241(2). Walgreens' claims on pages 13 through 15 of the Application therefore all lack merit.

CONCLUSION

Walgreens fails to present a single reason for the Board to withdraw or amend its Findings and Conclusions. The Board applied existing regulations, and thus did not engage in *ad hoc* rule making. The standards the Board used to measure Meyers's conduct are set by those regulations, such that no additional evidence is necessary to establish what those standards might be. Further, the circumstances of this case are such that Meyers had reason to do more than merely compare the pills in the bottle to the label and insert during verification. He was the first, and could have been the only, Nevada-licensed pharmacist to see the prescription. He was responsible for the work of the Walgreens's employees under his supervision. Nonetheless, Meyers failed to review the copy of the original prescription that was available to him. He therefore failed to follow the instructions of A.P.'s physician and incompetently, negligently or unskillfully contributed to dispensing the wrong medication to A.P. The Board should affirm its Findings and Conclusions and to hold Meyers partially responsible for that dispensing error.

DATED this 20th day of May, 2016.

S. Paul Edwards
General Counsel
Nevada State Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. TINA RIZZOLO, RPH Certificate of Registration No. 17665, LUCAS MEYERS, RPH Certificate of Registration No. 16064, WALGREENS PHARMACY #3922 Certificate of Registration No. PH01127, and WALGREENS MAIL SERVICE, INC. Certificate of Registration No. PH01964, Respondents.	Case Nos. 15-028-RPH-A-S 15-028-RPH-B-S 15-028-PH-S 15-028-PH-O **REPLY TO NEVADA BOARD OF PHARMACY'S RESPONSE TO AMENDED APPLICATION AND REQUEST FOR REHEARING**

Respondents, Lucas Meyers and Walgreens Pharmacy #3922 ("Respondents"), by and through William J. Stilling and Robert W. DeLong of and for Parsons Behle & Latimer, hereby reply to the Nevada Board of Pharmacy's ("Board") Response to Amended Application and Request for Rehearing.

I. INTRODUCTION

The Nevada Board of Pharmacy's Response to Amended Application and Request for Rehearing Response ("Board's Response") ignored the substance of Respondents' position that the Board impermissibly engaged in ad hoc rulemaking. The Board's Response recast Respondents' position as a claim that the Board improperly applied existing laws and rules. However, Respondents' explained that the Board engaged in ad hoc rulemaking by: (i) deciding a "question different from and broader than the question before the Board;" (ii) announcing "a standard of general applicability when it destroyed any benefit workload balancing has to alleviate

a pharmacy overwhelmed by a rush [of] prescriptions;" and (iii) "issuing 'a directive or statement of general applicability, which effectuates or interprets law or policy,'" without following the requirements of the Nevada Administrative Procedures Act ("Nevada APA"). *See* Amended Application and Request for Rehearing ("Rehearing Request") at pp. 2 through 5. The Board's Response further claimed the Board's decision was based on substantial evidence, but the only evidence it cited were laws and regulations that were absent from the Accusation in this case, which violated the Nevada APA's requirements that the notice in a contested case must contain "[a] reference to the particular sections of the *statutes and regulations involved.*" NRS §223B.121 2.c. (emphasis added). Finally, the Board claimed it treated Mr. Meyers as it would any other similarly situated pharmacist. To the contrary, the new policy deems Mr. Meyers' conduct to be unprofessional in the face of the Board's own regulation that expressly allows a Nevada fulfillment pharmacist to rely on the data verification by an out-of-state, non-Nevada-licensed pharmacist without risk of unprofessional conduct for the verifying pharmacist's mistake.

Respondents respectfully ask the Board to: (i) decide how it will treat pharmacists in segmented-filling processes through rulemaking; (ii) treat Respondents as it treats other similarly situated licensees; and (iii) forgo any reliance on laws and rules that the Board failed to include in the Accusation. In doing so, Respondents request the Board to reverse its initial conclusion and find Mr. Meyers not guilty under the First Cause of Action.

II. DISCUSSION

A. RESPONDENTS' AD HOC RULEMAKING CLAIM IS BASED ON THE BOARD'S CREATING A GENERALLY APPLICABLE POLICY THAT GOES FAR BEYOND THE FACTS AND CIRCUMSTANCES OF THIS CASE.

Contrary to the Board's assertion, Respondents did not base their ad hoc rulemaking objection on the Board's "not apply[ing] properly adopted regulations." *See* Board's Response at

p. 1 and Respondents' Request for Rehearing at pp. 1-5. Rather, Respondents contest the Board's creation of a new regulation. The Nevada Administrative Procedures Act ("Nevada APA") defines a "regulation" to include:

> (a) An agency rule, standard, directive ***or statement of general applicability which effectuates or interprets law or policy***, or describes the organization, procedure or practice requirements of any agency . . . . and
>
> (d) The general application by an agency of a written policy, interpretation, process or procedure to determine whether a person is in compliance with a federal or state statute or regulation in order to assess a fine, monetary penalty or monetary interest.[1]

NRS § 233B.038 (emphasis added). The Nevada Supreme Court has made it clear that an agency cannot escape public input and Legislative Counsel review by promulgating a regulation under the guise of an administrative decision in a specific case. *See Coury v. Whittlesea-Bell Luxury Limousine*, 721 P.2d 375 (Nev. 1986) (agency's adjudicative decision constituted ad hoc rulemaking because agency's order was "of such major policy concern and of such significance" to regulated entities "it cannot be characterized as a simple adjudication in a contested case and thus outside of the statutory definition of a regulation.") *Public Serv. Comm'n of Nevada v. Southwest Gas Corp.*, 662 P.2d 624 (Nev. 1983) ("Although the order changing Southwest's rate design is directed to Southwest only, it certainly has a 'general applicability' which affects other gas utilities and their customers.").

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[1] Since the Findings were entered in this case, the Board has used this case as the basis for asserting causes of action and reaching stipulated settlements. Such use exemplifies the Board's view that its broad announcement of liability for all pharmacists who handle a prescription after the data-entry pharmacist applies generally to all segmented filling systems. *See e.g., Nevada Board of Pharmacy v. Black, Goodman,, and Omnicare of Las Vegas,* Cases 13-067.

In this case, the Board announced its intention to make this case about broad policies that extend beyond the discreet facts of this case.

> With written stipulations in the record as to the facts and a majority of the causes of action, ***only two issues remained open for decision by the Board during the hearing: Those two questions are***:
>
> (1) Whether a pharmacist who participates in a segmented prescription filling process is responsible for an error that a previous pharmacist in that process failed to detect and subsequently approved as accurate; and
>
> (2) Whether a pharmacy that dispenses an incorrect medication under the circumstances described in issue one above is responsible for that dispensing error.

See Findings and Conclusions at p. 2 (emphasis added). These sweeping statements about what the Board would decide by finding Mr. Meyers guilty apply generally to any pharmacy with any segmented system and any pharmacist who touches a prescription during filling or refilling.[2] Respondents direct Board members to read pages 2 through 5 of Respondents Amended Application and Request for Rehearing ("Rehearing Request") in which they detail why this sweeping announcement is a "statement of general applicability which effectuates or interprets law or policy." NRS § 22B.038 1.(d). By issuing this statement of general policy and effectively creating a regulation, the Board circumvented the requirements of the Nevada APA. The decision deprived regulated entities and the public of having any opportunity to participate in a workshop (NRS § 223B.061 2.) or to provide their views at a public hearing (NRS § 223B.061 3). The Board

[2] The Board's statement treats pharmacies and pharmacists with segmented-filling systems more onerously than pharmacies and pharmacists without such systems. Under the Board's announcement, a pharmacist filling the third refill in a segmented-filling system would be liable for a misdispensing that resulted from a data-verifying pharmacist's error. The pharmacist in the non-segmented system would not be liable.

also avoided the mandatory submission to, and review and approval by, Legislative Counsel. (NRS § 223B.063, 0635, and 064).

At bottom, the Board created a "statement of general applicability, which effectuates or interprets law or policy" because the Findings announce a new interpretation of NAC 639.945 (1) (d) and (i) that applies prospectively to all licensees who handle prescriptions in a segmented filling system. Those pharmacists who come before the Board and have handled such prescriptions (original fills or any subsequent refill) after a data-checking pharmacist errs will be guilty of unprofessional conduct. NRS § 223B.038(a). By doing so, the Board shortcut the very protections the Nevada APA rulemaking provisions are intended to avoid—an agency creating regulations that will apply to individuals and businesses without allowing those individuals and businesses the opportunity to provide input at a workshop and public hearing and without allowing Legislative Counsel the opportunity to ensure the policy comports with Nevada law. As such, the Board's decision violates the Nevada APA and is beyond the Board's statutory authority. *See* NRS §223B.135 (a) through (d).

B. THE NEWLY PROCLAIMED STANDARD IS ARBITRARY AND CAPRICIOUS.

A decision is "[a]n arbitrary or capricious exercise of discretion" if it is "founded on prejudice or preference rather than on reason or contrary to the evidence or established rules of law." *State v. Eighth Judicial Dist. Court*, 127 Nev. 927, 932, 267 P.3d 777, 780 (2011). The Board's decision is contrary to established rules of law because it violated the Nevada APA. As described below, the decision is based on preference because the decision treats Mr. Meyers and Walgreens differently than similarly situation pharmacists and pharmacies without any basis for such disparate treatment.

1. The Newly Proclaimed Standard Contradicts Regulations that Expressly Allow One Data-Entry Check by an Unlicensed Out-of-State Pharmacist for Fulfillment Pharmacy Arrangements.

Nevada's fulfillment pharmacy regulation expressly allows one pharmacist in a segmented system[3] to verify the data entry of a prescription without liability for the product checking pharmacist. NRS §639.7125 ("Fulfillment Regulation"). The Fulfillment Regulation allows a fulfillment pharmacy to fill a first-time prescription for a dispensing pharmacy if "[a] pharmacist employed by the dispensing pharmacy ***or*** a pharmacist employed by the fulfillment pharmacy verifies the correctness of the data in the computer system of the dispensing pharmacy concerning the prescription before the prescription is filled by the fulfillment pharmacy . . ." NAC §639.7125 1. (e)(1) (emphasis added). The Fulfillment Regulation provides that each pharmacy is responsible for its own errors:

> If a prescription is transmitted to and filled or refilled by a fulfillment pharmacy pursuant to this section, both the dispensing pharmacy and the fulfillment pharmacy are ***individually responsible for ensuring that their respective portions of the prescription have been filled or refilled correctly.***

Id. at 4 (emphasis added).

Board staff reiterated the meaning and intent of the liability allocating section at the same January Board meeting during which it heard the instant matter. Two pharmacies (South Dakota dispensing pharmacy and Nevada fulfillment pharmacy) came to the Board seeking clarification

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[3] By the dictionary definition of "segment," a fulfillment-dispensing pharmacy relationship is a segmented system because the process is divided into parts. The dispensing pharmacy receives a prescription, conducts data verification, and then sends a prescription to the fulfillment pharmacy for a product check and delivery to the patient. *See* NRS §639.7125 9 (a) and (b) (definitions of "dispensing pharmacy" and "fulfillment pharmacy").

The Board's use of the term "segmented filling process" reveals another reason public input and Legislative Counsel review are essential. The Board's announcement is impermissibly vague by failing to define that key term. The dictionary definition referenced above provides little limitation on what segmented means as the term serving as the basis for unprofessional conduct.

of a rule so they could operate under NAC 639.7125. Someone raised the issue of who must verify the data entry and who is at fault for a data-entry error. Dave Wuest, the Board's Assistant Executive Director, affirmed that only one pharmacist needed to verify the data and that if a mistake in verifying data occurs, the pharmacist who makes the data error mistake is responsible, not the other pharmacy, even when the data verification pharmacist is not licensed by Nevada. Importantly, the Board expressed the exact same concern regarding its ability to sanction pharmacists at an out-of-state dispensing pharmacy under the Fulfillment Regulation as it raised in this case about the Florida data-checking pharmacist.

> Cheryl Blomstrom: Are the pharmacists at Tel Drug licensed in Nevada also in addition to the pharmacy?
>
> Ed Rickert: [Inaudible] No, there's no requirement.
>
> Cheryl Blomstrom: But, we don't have a nexus to them? We only have a nexus to their pharmacy?
>
> Dave Wuest: Yeah, that's what I was going to say. So in that model, just so we can walk through it real quick, if an error happened on data entry, we would have an action against the pharmacy, but no pharmacist. And, if it happened under, in Nevada, you would have an action with the dispensing pharmacist and the pharmacy.

See Recording of discussion of Item 15, BriovaRx of Nevada, LLC and Tel-Drug, Inc., on January 13-14, 2016 Agenda at 16:10. As it should, Board staff stood squarely behind the Fulfillment Regulation wherein "the responsibility is placed on . . . whoever did the activity." *See* Recording of discussion of Item 15 on January 13-14, 2016 Agenda (BriovaRx of Nevada, LLC and Tel-Drug, Inc.) at 18:15 (Mr. Wuest clarifying the allocation of liability).

The Fulfillment Regulation demonstrates that the Board understands it must use the processes mandated by the Nevada APA when it determines how responsibility will be allocated between pharmacies and pharmacists that undertake different parts of the prescription filling

process (i.e., a segmented filling system). The Board therefore cannot now decide to issue a general policy that allocates responsibility for the error of a data-checking pharmacist to any pharmacist who touches a prescription in any segmented filling system without going through the Nevada APA rulemaking requirements.

2. The Newly Announced Standard Treats Walgreens Unfairly by Imposing a Different Standard than the Board Applies to Similarly Situated Pharmacies.

The Board's Response explained that the "standards for measuring Meyer's conduct and all similarly situated pharmacists are already set by regulations." Response at p. 4. Mr. Meyers is similarly situated with pharmacists who process prescriptions for a fulfillment pharmacy using a segmented system. Yet, the Fulfillment Regulation allows the fulfillment pharmacists to rely on the data-entry verification by the dispensing pharmacy and allocates fault to whoever did the particular activity that led to an error. The Board unfairly applied a different standard, embodied in the newly announced standard, to Mr. Meyers. Diagram 1 illustrates the point.[4]

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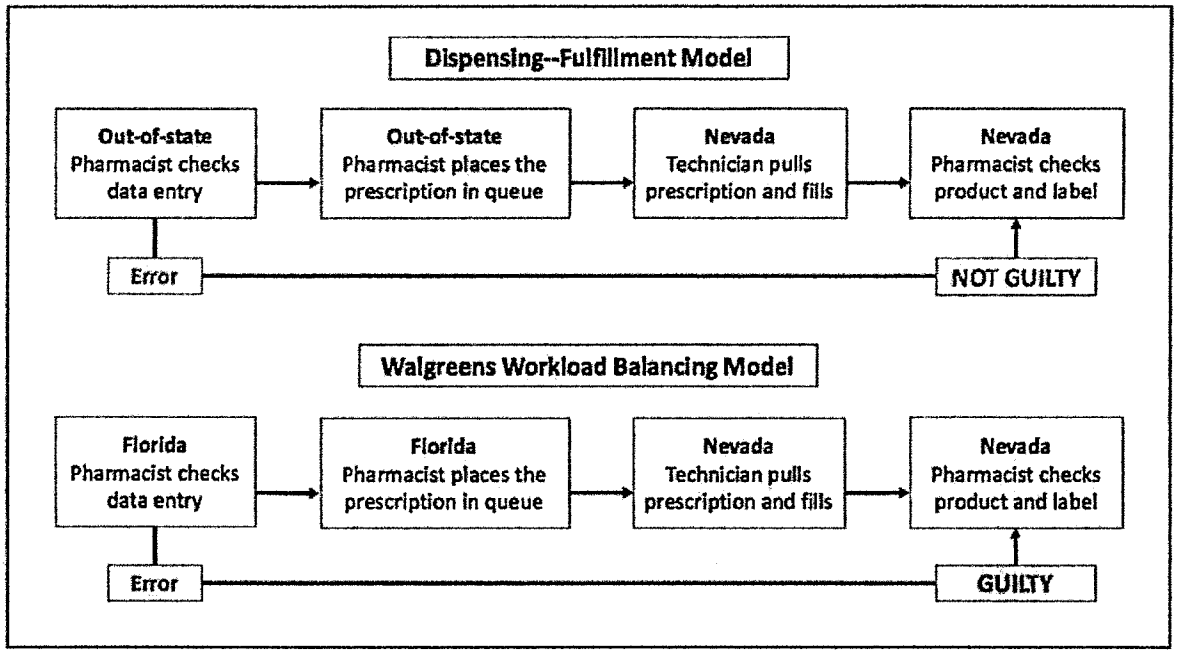
[4] At the BriovaRx discussion, Board staff made the point that the instant case did not arise under the Fulfillment Regulation. Even if that is true, it does not change the fact the Mr. Meyers is similarly situated to a pharmacist performing a product check in a fulfillment pharmacy. To treat Mr. Meyers differently therefore applies a different standard of practice to him, dictates the specific process by which Walgreens (and other pharmacies that use a segmented system) must fill prescriptions, and places Walgreens and other pharmacies at an economic disadvantage by requiring them to have pharmacists perform redundant work or do away with the workload balancing process altogether. Mail order pharmacies and fulfillment pharmacies that send thousands of prescriptions to Nevada residents use segmented systems in which one pharmacist checks data entry without a recheck by the product verification pharmacist without risk of sanction for unprofessional conduct by the Board.

DIAGRAM 1
DISPARATE UNFAIR RESULT FOR WALGREENS PHARMACIST



The Findings explained, "Mr. Meyer, as the pharmacist on duty, is likewise responsible for the error of Walgreens Mail serve employee Ms. Wagner—who, due to her unlicensed status in Nevada, the Board deems to be 'other personnel who are not pharmacists working in or for the pharmacy.'" Findings at ¶ 14. The Response makes much of the fact that Mr. Meyers could have been the only Nevada pharmacist to see the prescription at issue. Response at p. 6. Yet, the Fulfillment Regulation and the Board's affirmation of that regulation at the BriovaRx discussion amply demonstrate that the Board is comfortable with allowing a pharmacist only licensed in another state to conduct the sole data verification for a prescription handled by a pharmacist located in Nevada. Diagram 1 shows the same process occurs in the fulfillment pharmacy arrangement as occurred in the facts of this case.

3. The Fulfillment Regulations Belie any Claim the Newly Announced Standard is Based on Patient Safety.

The Fulfillment Regulation allows a single data entry check by an out-of-state pharmacist and expressly places blame for a data-checking error on whoever did the activity. NRS §639.7125 1. (e)(1) and (6). In creating the Fulfillment Rule, the Board considered patient safety and lawfully obtained public input and vetted the regulation through Legislative Counsel. The Board thoughtfully concluded that allocating fault to the person who made the error, not to every pharmacist who handles the prescription, is in the best interest of protecting the public and patient safety. Therefore, the Board's contrary decision to find Mr. Meyers responsible for the data entry error of another pharmacist, in a situation substantially similar to a fulfilling pharmacist under NAC § 963.7125 1.(e)(1), can have nothing to do with patient safety. If the Board believes it was wrong about protecting patients in the Fulfillment Regulation and wants to allocate responsibility to all pharmacists who handle the prescription after data entry, then it must use the same rulemaking process it used to create the current allocation of responsibility. But, logic precludes the Board from treating Mr. Meyers differently than a fulfillment pharmacist and claiming the reason is patient safety.

4. The Newly Announced Standard Destroys the Ability of a Pharmacy to Balance Workload.

If every pharmacist is responsible for the error of the data-verifying pharmacist, then each pharmacist will feel a responsibility to check each prescription against the original prescription order. The Board has recognized that workload balancing is a good option to alleviate pressure on pharmacists during peak patient volumes. *See* Request for Rehearing at n. 1. If every pharmacist checks the data entered by a technician against the original prescription, there is no point in having a pharmacist from outside the busy pharmacy performing data verification to alleviate workload.

At least one Board member also correctly recognized that requiring the last pharmacist to check the data entry would "defeat[] the whole point of workload balancing." *Id.*

5. The Newly Announced Standard Creates Perverse Incentives to Move Prescription Filling for Nevada Residents to other States Employing Pharmacists Not Licensed in Nevada.

With the Board's newly announced policy, Nevada pharmacists practicing in Nevada are treated disadvantageously relative to out-of-state mail order pharmacists and fulfillment pharmacies. The Board's decision in this case and in combination with the Fulfillment Regulation, leads to the following results and incentives...

a. A pharmacist ***who works in a Nevada fulfillment pharmacy has no responsibility*** to verify the data entered and checked by out-of-state personnel who are not licensed in Nevada.

b. A pharmacist ***who is not licensed in Nevada*** and who ***works in a segmented, non-resident mail order pharmacy located in another state is not responsible*** for an error that a previous pharmacist in that process failed to detect.

c. Every pharmacist ***who works in a Nevada pharmacy*** and "participates in a segmented prescription filling process [i.e., the product-checking pharmacist, the pharmacist who hands the prescription to the patient, and any pharmacist who refills a prescription] ***is responsible for an error that a previous pharmacist*** in that process failed to detect and subsequently approved as accurate."

d. No pharmacy can take pressure off a busy pharmacist because it would require a pharmacist located in Nevada to review the data another pharmacist has already reviewed. *See* item c above.

e. There is an economic advantage to move filling to out-of-state pharmacies because any pharmacist who touches a prescription in Nevada, with the exception of Fulfillment pharmacists, must re-verify every prescription or risk a license action.

The Board's new policy unfairly treats pharmacists physically located in Nevada, other than fulfillment pharmacists, differently than pharmacists filling for Nevada residents. The Board

recognized the complexity of allocating responsibility for misfilled prescriptions in segmented systems and multistate processes at the hearing to amend NAC 639.921 (sharing of information between two or more pharmacies) and tabled a relatively simple proposal in order to obtain additional input from industry about allocating responsibility in such systems. Respondents simply ask the Board to fairly judge them as similarly situated pharmacies and to consider Walgreens system for workload balancing along with the public input it seeks.

C. THE BOARD'S RELIANCE ON NAC 639.702 AND OTHER LAWS AND REGULATIONS AS THE AS EVIDENCE FOR THE STANDARD TO MEASURE MR. MEYERS' CONDUCT IS MISPLACED.

The Board cannot base its decision on laws and regulations that were not in the Accusation. The Board must comply with the Nevada APA and the Pharmacy Act. The Nevada APA requires that the notice to a respondent, "must include . . . [a] reference to the particular sections of the *statutes and regulations involved.*" NRS §223B.121 2.c. (emphasis added). The Pharmacy Act states: "The accusation must specify the statutes and regulations which the respondent is alleged to have violated, but must not consist merely of charges phrased in language of the statute or regulation." NRS § 639.241. The Board considered, and the Findings relied, on the following laws and regulations without giving notice in the Accusation that they were at issue.

a. NRS § 639.220 ("managing pharmacist is responsible for [pharmacist's] designee");

b. NAC 639.252 (supervising pharmacist responsible for prescriptions filled by technician);

c. NAC 639.702 (managing pharmacist is responsible for the acts of "technicians and other personnel");

d. NAC 639.268, NAC 639.945(2) (pharmacist responsible for acts of technician under supervision); and

e. NAC 639.467 (pharmacist responsible for acts performed by technician under pharmacist's supervision) as bases for its decision.

All of these laws and regulations were the basis for the Board's decision and therefore all of them were "statutes and regulations involved" per the Nevada APA (NRS § 223B.121 2.c) and were "statutes and regulations which the respondent is alleged to have violated" during the hearing. Pharmacy Act (NRS 639.241). In fact, The Findings even concluded that violations of these laws and regulations are grounds for discipline under NRS § 639.255. Accusation at ¶ 16 ("Those violations are grounds for discipline pursuant to NRS § 639.255" apparently referring to ¶¶ 11 through 15 that included references to the laws and regulations listed above).[5]

III. CONCLUSION

Respondents ask the Board to reverse its new policy on allocation of fault to every pharmacist who handles a prescription (including refills) after a mistake by the data-checking pharmacist's error in a segmented filling system and to treat Walgreens and its pharmacists like similarly situated pharmacists. If the Board wants to change regulations regarding allocation of fault, it should do so with public input. Because the Board relied on laws and regulations involved

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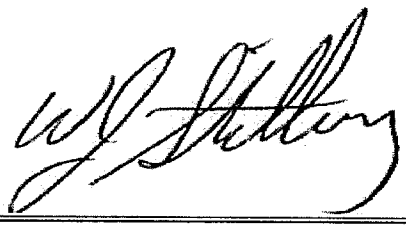
[5] Two statements in the Board's Response require correction. The Board's Response states that "Mr. Meyers testified during the hearing that he did not fulfill that responsibility because he did not look at the scanned copy of the prescription that was available to him to verify that Mallari selected the correct medication." Board's Response at p.4. Mr. Meyers never testified he did not fulfill his responsibility.

The other statement is at the bottom of page 5 continuing onto page 6 of the Board's Response: "Walgreen's adoption of a segmented filling system that deprives or discourages Meyers from fulfilling his duties does not excuse him from those responsibilities." First, this statement contracts the statement that the prescription was available to Mr. Meyers. Moreover, the statement contradicts paragraph 20 of the Board's Findings: "During the hearing, the Board made no findings or conclusions regarding Walgreens Retail's responsibility for Mr. Meyers' error. The Board hereby dismisses the Fourth Cause of Action as to that issue only." There is nothing in the record to support a statement that Walgreens deprived or discouraged any pharmacist from fulfilling the pharmacist's responsibilities. Rather, at various discussions during Board meetings since January, Board members have commented that Walgreens workload balancing system is a "good system" and that Walgreens is among the good companies with systems to detect and fix process errors. *See* Recording of March 2, 2016 D&D at 33:00 to the end.

in this case that were not included in the Accusation, the basis for finding Mr. Meyers liable was outside the law. Respondents, therefore, ask the Board to find Mr. Meyers not guilty.

DATED this _____ day of June, 2016.



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CERTIFICATE OF SERVICE

I hereby certify that on July 4, 2016, I caused to be served a true and correct copy of the foregoing **REPLY TO NEVADA BOARD OF PHARMACY'S RESPONSE TO AMENDED APPLICATION AND REQUEST FOR REHEARING** by the method indicated below to:

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- ☐ U.S. Mail postage prepaid
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