

JAN 28 2016

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

) CASE NO. 15-077-PT-S

Petitioner,

)

v.

)

KYLE KEKAUOHA, PT

)

Certificate of Registration No. PT13502,

)

NOTICE OF INTENDED ACTION
AND ACCUSATION

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 Respondent Kyle Kekauoha, PT (Mr. Kekauoha), Certificate of Registration No. PT13502, was a registered pharmaceutical technician with the Board at the time of the events alleged herein.

II.

On or about December 18, 2015, Board Staff received notification from Smith's Food and Drug Company's (Smith's) Pharmacy District Coordinator indicating that Smith's terminated Mr. Kekauoha from his employment as a pharmaceutical technician at Smith's Pharmacy #371. Smith's terminated Mr. Kekauoha's employment for diversion of controlled substances.

III.

During an interview conducted by the Smith's Pharmacy District Coordinator, and in a written statement, Mr. Kekauoha admitted to diverting modafinil tablets for the past year and a half. He diverted modafinil 100 mg. tablets and 200 mg. tablets for a combined total of approximately nine-hundred (900) tablets.

IV.

Mr. Kekauoha explained that he would modify the drug purchase order submitted to the pharmacy's supplier and add bottles of modafinil to the order. When the drug shipment was

delivered to the pharmacy, Mr. Kekauoha diverted the modafinil by putting the bottle(s) in the pocket of his pants.

V.

In his written statement, Mr. Kekauoha indicates that he diverted the drugs for personal use to stay awake during the night classes he is attending for school. He estimates that he ingests an average of 800 mg. per day.


FIRST CAUSE OF ACTION

VI.

By diverting controlled substances, namely, modafinil 100 mg. tablets and 200 mg. tablets, Mr. Kekauoha violated Nevada Revised Statute (NRS) 453.331(1)(d) and/or NRS 453.336(1), and/or Nevada Administrative Code (NAC) 639.945(1)(g) and/or (h), which violations are grounds for action pursuant to NRS 639.210(1), (4), (11), and/or (12), as well as 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 this respondent.

Signed this 28th day of January, 2016.


Larry L. Finson, 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.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 15-077-PT-S
)	
Petitioner,)	
v.)	
)	STATEMENT TO THE RESPONDENT
KYLE KEKAUOHA, PT)	NOTICE OF INTENDED ACTION
Certificate of Registration No. PT13502,)	AND ACCUSATION
)	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 (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 28th day of January, 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. 15-077-PT-S
)	
Petitioner,)	
v.)	
)	
KYLE KEKAUOHA, PT)	ANSWER AND NOTICE
Certificate of Registration No. PT13502,)	OF DEFENSE
)	
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.

KYLE KEKAUOHA, PT

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

SAV-ON PHARMACY #6060

Certificate of Registration No. PH02289,

Respondents.

CASE NO. 15-038-PH-S

NOTICE OF INTENDED
ACTION AND ACCUSATION

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

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Sav-On Pharmacy #6060 (Sav-On), Certificate of Registration No. PH02289, was a pharmacy registered with the Board.

II.

On or about June 1, 2015, Malik Ahmad, Esq., filed a consumer complaint with the Board Office on behalf of his client, patient R.K. The complaint alleges that Sav-On dispensed another patient's medication to R.K.

III.

Patient R.K. is a regular customer of Sav-On Pharmacy. She has a prescription filled monthly at Sav-On for levothyroxine¹ 25 mcg tablets.

IV.

On March 25, 2015, patient R.K.'s daughter picked up a refill of R.K.'s levothyroxine tablets from Sav-On.

¹ Levothyroxine is used for the treatment of hypothyroidism.

V.

R.K. ingested one (1) tablet per day for approximately five (5) days and began to experience headaches and dizziness.

VI.

On March 29, 2015, R.K. received a call from Sav-On that her medication was available for pick up. She allegedly found the call odd since her daughter picked up the medication on March 25, 2015.

VII.

The call from Sav-On prompted R.K. to examine the medication bottle that Sav-On dispensed to her daughter on March 25, 2015. She observed another patient's name on the prescription label.

VIII.

R.K. went to Sav-On and spoke with pharmacist Noor Dudekula. R.K. informed Mr. Dudekula that she received another patient's medication. She presented one tablet of the incorrect medication to him. Mr. Dudekula identified the tablet as hydrochlorthiazide² 12.5 mg.

IX.

Mr. Dudekula discovered R.K.'s levothyroxine prescription on the shelf in the pharmacy's out window queue. Mr. Dudekula then dispensed the correct medication to R.K.

X.

In a statement by Mr. Dudekula, the pharmacy video surveillance footage of March 25, 2015, shows that pharmaceutical technician Liliana Bernardino assisted R.K.'s daughter at the pharmacy out window. In a written statement, Ms. Bernardino admits that she mistakenly gave R.K. another patient's medication.

² Hydrochlorthiazide is a diuretic used for the treatment of high blood pressure and edema.

XI.

On March 30, 2015, R.K. was treated at the University Medical Center Urgent Care for symptoms related to dehydration induced by medication.

XII.

In failing to strictly follow the instructions of R.K.'s physician by dispensing *hydrochlorthiazide* 12.5 mg. tablets, rather than the *levothyroxine* 24 mcg. tablets R.K.'s physician prescribed, Sav-On's staff – particularly pharmacy technician Liliana Bernardino – violated Nevada Administrative Code (NAC) 639.945(1)(d) and (i).

FIRST CAUSE OF ACTION

XIII.

As the pharmacy in which the foregoing alleged violations occurred, Sav-On is statutorily responsible for the actions of its employee, Liliana Bernardino, 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.

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 8th 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.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	
)	CASE NO. 15-038-PH-S
)	
v.)	STATEMENT TO THE
)	RESPONDENT NOTICE
)	OF INTENDED ACTION
SAV-ON PHARMACY #6060)	AND ACCUSATION
Certificate of Registration No. PH02289,)	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, 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 8th day of March, 2016.


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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 15-038-PH-S
)	
Petitioner,)	
v.)	ANSWER AND NOTICE
)	OF DEFENSE
SAV-ON PHARMACY #6060)	
Certificate of Registration No. PH02289,)	
)	
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
SAV-ON PHARMACY #6060

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

RONALD HORVATH, RPH

Certificate of Registration No. 06097,

CVS PHARMACY #8791

Certificate of Registration No. PH01187,

Respondents.

CASE NO. 13-056-RPH-S

CASE NO. 13-056-PH-S

NOTICE OF INTENDED
ACTION AND ACCUSATION

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

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Ronald Horvath (Mr. Horvath), Certificate of Registration No. 06097, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #8791 (CVS), Certificate of Registration No. PH01187, was a pharmacy registered with the Board.

II.

On September 18, 2013, patient K.C.'s physician prescribed a quantity of thirty (30) bupropion 150 mg. XL (extended release) tablets with instructions to take one tablet by mouth every morning.

III.

The physician's office electronically transmitted the prescription to CVS. CVS filled the prescription later that same day.

IV.

On September 21, 2013, K.C. picked up the prescription from CVS (prescription No. 756119). Prescription No. 756119 was a new prescription. Pharmacy records indicate that K.C. declined patient counseling when she purchased the medication.

V.

A month later, on October 21, 2013, K.C. telephoned CVS to order a refill of prescription No. 756119. When K.C. opened the bottle of the refilled medication, she noticed the tablets differed from the tablets dispensed to her a month earlier.

VI.

K.C. telephoned CVS and spoke with the pharmacist on duty. The pharmacist confirmed that the medication dispensed in September contained **bupropion 150 mg. SR** (*sustained release*) tablets rather than the **bupropion 150 mg. XL** (*extended release*) tablets as prescribed.¹

VII.

K.C. ingested thirty (30) tablets of the incorrect medication over a thirty (30) day period with no reported adverse effects.

VIII.

According to pharmacy records, the filling error originated with pharmaceutical technician Kellie Batallones (Ms. Batallones), who performed the data entry for K.C.'s prescription No. 756119. During data entry, Ms. Batallones inadvertently entered **bupropion 150 mg. SR tablets** rather than the **bupropion 150 mg. XL tablets** as prescribed by K.C.'s physician.

IX.

Ms. Batallones completed the filling process and staged the final product for the pharmacist's verification.

¹ The **XL** dose is released into the body for a period of **24 hours**. The **SR** formulation is released into the body for a period of **12 hours**.

X.

Mr. Horvath performed the final product verification of prescription No. 756119. At the final verification, Mr. Horvath failed to identify the medication error.

FIRST CAUSE OF ACTION

XI.

In failing to strictly follow the instructions of K.C.'s physician by verifying and dispensing a prescription for *bupropion 150 mg. SR tablets* rather than *bupropion 150 mg. XL tablets* as prescribed, Mr. Horvath violated Nevada Administrative Code (NAC) 639.945(1)(d) and/or (i), which violations are grounds for action pursuant to Nevada Revised Statute (NRS) 639.210(4), (11), and/or (12), and NRS 639.255.


SECOND CAUSE OF ACTION

XII.

As the pharmacy in which the violations alleged above occurred, CVS is statutorily responsible for the actions of its employee, Respondent Ronald Horvath, 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.

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 8th 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.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 13-056-RPH-S
)	
v.)	
)	
Petitioner,)	
)	
)	STATEMENT TO THE
)	RESPONDENT NOTICE
RONALD HORVATH, RPH)	OF INTENDED ACTION
Certificate of Registration No. 06097,)	AND ACCUSATION
)	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, 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 8th 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. 13-056-RPH-S
)	
Petitioner,)	
v.)	ANSWER AND NOTICE
)	OF DEFENSE
RONALD HORVATH, RPH)	
Certificate of Registration No. 06097,)	
)	
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.

RONALD HORVATH, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 13-056-PH-S
)	
Petitioner,)	
v.)	ANSWER AND NOTICE
)	OF DEFENSE
CVS PHARMACY #8791)	
Certificate of Registration No. PH01187,)	
)	
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
CVS PHARMACY #8791

FILED

MAR 10 2016

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

SHARONA SOLEYMANI, RPH

Certificate of Registration No. 17116,

MALCOLM L. FIGERT, RPH

Certificate of Registration No. 03547,

HUNTRIDGE DRUG

Certificate of Registration No. PH02165,

Respondents.

CASE NO. 13-058-RPH-A-S

CASE NO. 13-058-RPH-B-S

CASE NO. 13-058-PH-S

NOTICE OF INTENDED

ACTION AND ACCUSATION

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

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein Respondent Sharona Soleymani, R.Ph. (Ms. Soleymani), Certificate of Registration No. 17116, and Respondent Malcolm Figert, R.Ph., (Mr. Figert), Certificate of Registration No. 03547, were both pharmacists registered with the Board, and Respondent Huntridge Drug (Huntridge), Certificate of Registration No. PH02165, was a pharmacy registered with the Board.

II.

In November 2013, Donna Jordan, CPM (Ms. Jordan), Clinical Program Manager at Southern Nevada Adult Mental Health Services (SNAMHS), filed a consumer complaint with the Board Office on behalf of patient W.K. The complaint alleges that Huntridge filled a prescription for patient W.K. with the wrong medication.

III.

Per the Complaint, on October 10, 2013, patient W.K.'s physician prescribed a quantity of one-hundred and twenty (120) *Navane 10 mg. tablets* with instructions to take one (1) tablet by mouth every morning and three (3) tablets at bedtime. The handwritten prescription included three additional medications prescribed to W.K.

IV.

Huntridge accepted the prescription and filled it on October 10, 2013.

V.

W.K. picked up the medications from Huntridge the following day. Pharmacy records indicate that W.K. declined patient counseling when he purchased the medications.

VI.

On October 31, 2013, SNAMHS nurse K.G. received a fax from Huntridge asking if a doctor from SNAMHS prescribed amlodipine (Norvasc) to patient W.K. Nurse K.G. contacted Huntridge and learned from pharmaceutical technician S.S. that Huntridge had erroneously filled and dispensed *Norvasc* to W.K., rather than the *Navane* his physician prescribed.¹

VII.

Respondent Ms. Soleymani contacted W.K. to inform him of the medication error. W.K. returned the erred medication to Huntridge, which replaced it with the correct medication.

VIII.

W.K. ingested four tablets a day of the incorrect medication for approximately three weeks with no reported adverse effects.

IX.

The dispensing error originated with Ms. Soleymani, who performed the data entry for W.K.'s prescription no. 6041904. During data entry, Ms. Soleymani inadvertently entered

¹ *Navane* is an antipsychotic used for the treatment of schizophrenia. *Norvasc* is a calcium channel blocker used for the treatment of hypertension and coronary artery disease.

Norvasc (amlodipine) 10 mg. tablets rather than the *Navane 10 mg. tablets* as prescribed by W.K.'s physician.

X.

Ms. Soleymani completed the filling process and performed product verification. She did not detect the medication error during final product verification.

XI.

Rather than placing the medication that W.K. returned in quarantine for appropriate disposal, Huntridge pharmacy staff placed it in a location that allowed it to be returned to stock.

XII.

While working under the supervision of Respondent Mr. Figert, pharmaceutical technician Lindsay Cloutier (also known as Lindsay Walker)² returned the medication to stock in violation of Nevada Administrative Code (NAC) 639.760(4).

FIRST CAUSE OF ACTION

XIII.

In failing to strictly follow the instructions of W.K.'s physician by verifying and dispensing *Norvasc (amlodipine) 10 mg. tablets*, rather than the *Navane 10 mg. tablets* as prescribed by W.K.'s physician, Ms. Soleymani violated Nevada Administrative Code (NAC) 639.945(1)(d) and/or (i), which violations are grounds for action pursuant to Nevada Revised Statute (NRS) 639.210(4), (11), and/or (12), and NRS 639.255.

SECOND CAUSE OF ACTION

XIV.

As the pharmacy in which its employee, Respondent Ms. Soleymani, dispensed the incorrect medication to patient W.K., as alleged above, Huntridge Drug is responsible for the

² Ms. Walker registered as a pharmaceutical technician with the Nevada Board under the last name of "Cloutier." She reported a name change to "Walker" on January 21, 2016.

error 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.

THIRD CAUSE OF ACTION

XV.

As the supervising pharmacist at the time pharmaceutical technician Lindsay Cloutier returned previously dispensed medication back to the pharmacy's stock in violation of NAC 639.760(4) and (5), Malcolm Figert, R.Ph., is responsible for that error pursuant to NAC 639.702, which is grounds for discipline pursuant to Nevada Revised Statute (NRS) 639.210(4) and (12) and NRS 639.255.


FOURTH CAUSE OF ACTION

XVI.

As the pharmacy in which pharmaceutical technician Lindsay Cloutier violated NAC 639.760(4) and (5) by returning previously dispensed medication back to the pharmacy's stock, Huntridge Drug is responsible for that violation pursuant to NAC 639.702 and NAC 639.945(2), which is grounds for discipline pursuant to NRS 639.210(4) and (12), as well as 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 8th 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.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	
)	CASE NO. 13-058-RPH-A-S
)	
v.)	
)	STATEMENT TO THE
)	RESPONDENT NOTICE
SHARONA SOLEYMANI, RPH)	OF INTENDED ACTION
Certificate of Registration No. 17116,)	AND ACCUSATION
)	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, 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 8th day of March, 2016.


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

JACOB L. HAFTER, ESQ.
Nevada Bar No. 9303
HAFTERLAW
6851 W. Charleston Boulevard
Las Vegas, NV 89117
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*Counsel for Respondents
Huntridge Drug, Sharona Soleymani, RPH and
Malcolm L Figert, RPH*

**BOARD OF PHARMACY
STATE OF NEVADA**

NEVADA STATE BOARD OF PHARMACY,
Petitioner,
vs.

CASE NO. 13-058-RPH-A-S
CASE NO. 13-058-RPH-B-S
CASE NO. 13-058-PH-S

SHARONA SOLEYMANI, RPH
Certificate of Registration No. 17116,

MALCOLM L. FIGERT, RPH
Certificate of Registration No. 03547,

HUNTRIDGE DRUG
Certificate of Registration No. PH02165,

Respondents.

**ANSWER AND NOTICE OF
DEFENSE, AND REQUEST FOR
HEARING**

COMES NOW Respondents **HUNTRIDGE DRUG, SHARONA SOLEYMANI, RPH, and MALCOLM L. FIGERT**, by and through their counsel, Jacob Hafter, Esq., of **HAFTERLAW**, to answer to the Nevada State Board of Pharmacy's Notice of Intended Action and Accusation, as follows:

1. As to paragraphs 2, 3, 6, and 8 of the Board of Pharmacy's Notice of Intended Action and Accusation, Respondents are **without sufficient knowledge** or information to form a belief as to the truth or falsity of the matters alleged.



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2. As to paragraphs 11 through 16 of the Board of Pharmacy's Notice of Intended Action and Accusation, this paragraph contains characterizations of this action and **conclusions of law**, not allegations of fact, and thus no response is required. To the extent a response is deemed necessary, Respondents deny the allegations contained in paragraphs 11 through 16.

3. As to paragraph 9 of the Board of Pharmacy's Notice of Intended Action and Accusation, Respondents **deny** the allegations contained therein, and are without sufficient knowledge or information to form a belief as to the truth or falsity of the matters alleged with respect to the other parties.

4. As to paragraphs 1, 4-5, 7, and 10 of the Board of Pharmacy's Notice of Intended Action and Accusation, Respondents **admit** the allegations contained in paragraphs 1, 4-5, 7, and 10,

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

The Complaint fails to state a legally cognizable claim under NRS Chapter 630 for which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

(Denial of Fundamental Due Process)

For each Count, the Complaint fails to state facts that would give Respondents sufficient notice of the charges to which she must answer to enable them to prepare a meaningful defense thereto as required by NRS §630.339(1).

THIRD AFFIRMATIVE DEFENSE

(Lack of Intent)

Certain causes of action of the Complaint require that Respondent be shown to have *mens rea* or an intent to deceive and no intent is alleged.

1 **FOURTH AFFIRMATIVE DEFENSE**

2 **(No Patient Harm)**

3 None of the Counts or allegations in the Complaint support any facts that would show
4 the patient was harmed.

5
6 **FIFTH AFFIRMATIVE DEFENSE**

7 **(Statute of Limitations / Laches)**

8 The Complaint was filed beyond the applicable statute of limitations for one or more
9 causes of action, or, generally violates the equitable principles of laches.

10
11 **SIXTH AFFIRMATIVE DEFENSE**

12 **(Acts of Others)**

13 The occurrences referred to in the Complaint, and all damages, if any, resulting
14 therefrom, or caused by the actions or omissions of another party to this suit, a third party, or
15 parties and/or entities, over whom answering Respondents had no control.

16
17 **SEVENTH AFFIRMATIVE DEFENSE**

18 **(Undue Delay in Bringing Claims)**

19 The claims made by the Petitioner are barred by the doctrines of estoppel, waiver,
20 acquiescence and/or laches.

21
22 **EIGHTH AFFIRMATIVE DEFENSE**

23 **Unjust Enrichment**

24 The Court would unjustly enrich the Petitioner by granting the relief sought herein.
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NINTH AFFIRMATIVE DEFENSE

Reservation of Other Defenses and Right to Bring Counterclaim

Respondents hereby reserve the right to amend this pleading to include other affirmative defenses, and bring a counterclaim as may be required, as this matter proceeds through discovery.

WHEREFORE, Respondents respectfully request the following relief:

1. That a hearing be set in this matter with adequate time for Petitioners to investigate the claims, secure witnesses and coordinate a viable defense;
2. That following said hearing that this action be dismissed with prejudice; and,
3. That Board award Respondent's attorneys' fees and costs to defend this litigation.

Dated this 25th day of March, 2016.

HAFTERLAW

By: _____

Jacob L. Hafter, Esq.
Nevada Bar Number 9303
Counsel for Respondents

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HAFTERLAW

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General Counsel
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E-mail: pedwards@pharmacy.nv.gov**

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FOURTH AFFIRMATIVE DEFENSE

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The Complaint was filed beyond the applicable statute of limitations for one or more causes of action, or, generally violates the equitable principles of laches.

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The occurrences referred to in the Complaint, and all damages, if any, resulting therefrom, or caused by the actions or omissions of another party to this suit, a third party, or parties and/or entities, over whom answering Respondents had no control.

SEVENTH AFFIRMATIVE DEFENSE

(Undue Delay in Bringing Claims)

The claims made by the Petitioner are barred by the doctrines of estoppel, waiver, acquiescence and/or laches.

EIGHTH AFFIRMATIVE DEFENSE

Unjust Enrichment

The Court would unjustly enrich the Petitioner by granting the relief sought herein.

1 **NINTH AFFIRMATIVE DEFENSE**

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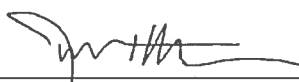
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16 By:

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19 Jacob L. Hafter, Esq.
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21 *Counsel for Respondents*

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NEVADA STATE BOARD
OF PHARMACY

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

XIV.

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

XV.

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

XVI.

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

XVII.

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

XVIII.

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

XIX.

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

XX.

Pathway did not list sterilization procedures on its compounding worksheets.

XXI.

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

FIRST CAUSE OF ACTION

Failure to Keep Accurate Records

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

XXII.

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

SECOND CAUSE OF ACTION

Failure to Conduct Required Testing

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

XXIII.

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

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

THIRD CAUSE OF ACTION

Sterilization Technique

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

XXIV.

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

FOURTH CAUSE OF ACTION

Managing Pharmacist Responsibilities

(Respondent Daniel Shalala)

XXV.

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

FIFTH CAUSE OF ACTION

Staff Working Outside Scope of Training

(Pathway Specialty Compounds)

XXVI.

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

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

XXVII.

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

SEVENTH CAUSE OF ACTION
Pharmacy Responsibility
(Pathway Specialty Compounds)

XXVIII.

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


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

XXIX.

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

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

Signed this 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,

Petitioner,

v.

DANIEL SHALALA, RPH

Certificate of Registration No. 15615

Respondent.

) **STATEMENT TO THE RESPONDENT**

) **NOTICE OF INTENDED ACTION**

) **AND ACCUSATION**

) **RIGHT TO HEARING**

)

) **CASE NO. 14-073-RPH-A-S**

)

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/

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

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	ANSWER AND
)	NOTICE OF DEFENSE
Petitioner,)	
v.)	
)	
DANIEL SHALALA, RPH)	CASE NO. 14-073-RPH-A-S
Certificate of Registration No. 15615)	
)	
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 March, 2016.

DANIEL SHALALA, R.PH.

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	ANSWER AND
)	NOTICE OF DEFENSE
Petitioner,)	
v.)	
)	
CHRISTOPHER PETERS, RPH)	CASE NO. 14-073-RPH-B-S
Certificate of Registration No. 16325)	
)	
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 March, 2016.

CHRISTOPHER PETERS, R.PH.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	ANSWER AND
)	NOTICE OF DEFENSE
Petitioner,)	
v.)	
)	
KELLY GREEN, RPH)	CASE NO. 14-073-RPH-C-S
Certificate of Registration No. 10331)	
)	
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 March, 2016.

KELLY GREEN, R.PH.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	ANSWER AND
)	NOTICE OF DEFENSE
Petitioner,)	
v.)	
)	
PATHWAY SPECIALTY COMPOUNDS)	CASE NO. 14-073-PH-S
Certificate of Registration No. PHC02590)	
)	
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 March, 2016.

Type or print name

AUTHORIZED REPRESENTATIVE FOR
PATHWAY SPECIALTY COMPOUNDS