BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 15-075-RPH-S**
	)	**15-075-PH-S**
Petitioner,	)	
v.	)	
	)	
RHOWELA ALBANA, RPH	)	**NOTICE OF INTENDED ACTION**
Certificate of Registration No. 18334	)	**AND ACCUSATION**
	)	
CVS PHARMACY #8789	)	
Certificate of Registration No. PH01257	)	
	)	
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.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these respondents because at the time of the alleged events, Respondent Rhowela Albana (Ms. Albana) was a pharmacist licensed by the Board, and Respondent CVS Pharmacy #8789 (CVS) was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

II.

On December 4, 2015, Tiffany Russaw, APRN, filed a complaint with the Board Office alleging that CVS Pharmacy filled and dispensed the the wrong medication to patient C.J.

III.

On October 30, 2015, C.J. saw APRN Russaw, who prescribed a quantity of thirty (30) mirtazapine with instructions to take one tablet daily at bedtime.

IV.

C.J. tendered the prescription to CVS on November 4, 2015. CVS assigned it prescription #1275047, and dispensed the medication that day.

V.

On December 3, 2015, C.J. contacted Russaw indicating that CVS did not dispense mirtazapine to her as prescribed. The label on the prescription bottle indicated that CVS instead dispensed temazepam 30 mg. capsules.

VI.

In an effort to verify C.J.'s complaint, Russaw accessed C.J.'s PMP Patient Utilization Report and found that CVS dispensed temazepam to C.J. on November 4, 2015.

VII.

Russaw never prescribe temazepam for C.J.

VIII.

Russaw next contacted CVS and spoke with pharmacist Chester Dudzik (Mr. Dudzik), who confirmed CVS's November 4, 2015 dispensing error.

IX.

CVS's records show that the error began when pharmaceutical technician Stefanie Wendel entered the data for Prescription NO. 1275047 and inadvertently selected temazepam[1] (Restoril) 30 mg. capsules, rather than the mirtazapine[2] (Remeron) 30 mg. tablets Russaw prescribed.

X.

Ms. Albana failed to detect that the medication in the bottle was not the medication Russaw prescribed and verified temazepam as accurate.

[1]Temazepam is a benzodiazepine used to treat insomnia symptoms.

[2]Mirtazapine is an antidepressant used to treat major depressive disorder.

XI.

C.J. accepted counseling, where Ms. Albana again failed to detect that CVS was dispensing the wrong medication.

XII.

During the Board's investigation of this matter, Ms. Albana told the Board Investigator that the scanned image of the prescription is small and that she may have misread the drug name during counseling.

XIII.

C.J. returned the temazepam to CVS on December 4, 2015. She had not ingested any of the wrong medication.

XIV.

CVS replaced the erred medication that same day with the mirtazapine as prescribed.

FIRST CAUSE OF ACTION

XV.

NAC 639.945(1)(d) defines unprofessional conduct to include the failure by a licensee to follow strictly the instructions of a prescriber when filling, labeling and dispensing a prescription. Unprofessional conduct also includes performing duties in an "incompetent, unskillful or negligent manner" *See* NAC 639.945(1)(i). Ms. Albana violated NAC 639.945(1)(d) and/or (i) by verifying, labeling and dispensing temazepam 30 mg. capsules to C.J., when her prescriber prescribed mirtazapine 30 mg. tablets.

SECOND CAUSE OF ACTION

XVI.

NRS 639.266 requires a pharmacist, on receipt of a prescription and after review of the patient's record, to communicate with the patient, or a person caring for the patient, matters that will enhance the patient's therapy through drugs. NAC 639.707(1) and (2) require that discussion to include, among other things, the name of the drug, dosage and administration

instructions, the intended use of the drug, common side effects, and other information that is necessary for the safe and effective use of the drug. Further, NAC 639.945(1)(i) defines unprofessional conduct to include performing duties in an "incompetent, unskillful or negligent manner" See NAC 639.945(1)(i).

Here, Ms. Albana violated NRS 639.266, NAC 639.707(1) and (2), and NAC 639.945(1)(i), when she failed to adequately counsel C.J. regarding temazepam 30 mg. capsules, which was a new medication to her.

THIRD CAUSE OF ACTION

XVII.

NAC 639.945(2) states that "[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". Repondent Ms. Albana is CVS's employee. As such, CVS is responsible for each of the violations alleged herein.

XVIII.

The violations alleged above, including in each cause of action, are grounds for discipline against the licenses of Rhowela Albana and or CVS #8789 pursuant to NRS 639.210(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 certificates of registration of these respondents.

Signed this ___ day of August, 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,	)	**STATEMENT TO THE RESPONDENT**
	)	**NOTICE OF INTENDED ACTION**
Petitioner,	)	**AND ACCUSATION**
v.	)	**RIGHT TO HEARING**
	)	
RHOWELA ALBANA, RPH	)	**CASE NO. 15-075-RPH-S**
Certificate of Registration No. 18334	)	
	)	
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, October 12, 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 17th day of August, 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.	)	
	)	
RHOWELA ALBANA, RPH	)	**CASE NO. 15-075-RPH-S**
Certificate of Registration No. 18334	)	
	)	
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 August, 2016.

RHOWELA ALBANA, R.PH.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**ANSWER AND**
	)	**NOTICE OF DEFENSE**
Petitioner,	)	
v.	)	
	)	
CVS PHARMACY #8789	)	**CASE NO. 15-075-PH-S**
Certificate of Registration No. PH01257	)	
	)	
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 August, 2016.

_____
Type or print name

_____
AUTHORIZED REPRESENTATIVE FOR
CVS PHARMACY #8789

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	**CASE NOS. 16-087-RPH-S**
Petitioner,	
v.	
	NOTICE OF INTENDED ACTION AND ACCUSATION
PAMELA KALYAN, R.PH.	
Certificate of Registration No. 15083	
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 because at the time of the events alleged herein, Respondent Pamela Kalyan (Ms. Kalyan), Certificate of Registration No.15083, was a registered pharmacist with the Board.

II.

On October 31, 2016, Meds Direct Rx of NV's (Meds Direct) pharmacy registration expired due to non-renewal of its Nevada pharmacy license with the Board.

III.

Meds Direct continued to operate the pharmacy without being properly licensed or registered with the Board for approximately thirty days (30) from November 1, 2016, through November 30, 2016. *See* NRS 639.100 (requiring an entity to hold a pharmacy license when operating a pharmacy in Nevada).

IV.

On or about December 1, 2016, the Board Office received a *Renewal Application – PHARMACY* form and late renewal fee from Meds Direct.

V.

On or about December 2, 2016, Board Staff served Meds Direct with a citation in the amount of $3,000.00 for operating a pharmacy without a current pharmacy license.

VI.

Respondent Pamela Kalyan was the managing pharmacist during the period that Meds Direct operated without being properly licensed or registered with the Board.

FIRST CAUSE OF ACTION

VII.

As the pharmacist in charge of a pharmacy that operated for approximately thirty (30) days from November 1, 2016, through November 30, 2016, without being properly licensed or registered with the Board, Pamela Kalyan is subject to discipline pursuant to Nevada Revised Statute (NRS) 639.230(5), as well as Nevada Administrative Code (NAC) 639.945(1)(i) and/or (j), which violations are grounds for discipline pursuant to NRS 639.210(4), (11), (12), and/or (13), or alternatively, under NRS 639.255, as well as NAC 639.955.

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 2nd day of December, 2016.

Larry 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. 16-087-RPH-S**
	)	
Petitioner,	)	
v.	)	**STATEMENT TO THE RESPONDENT**
	)	**NOTICE OF INTENDED ACTION**
	)	**AND ACCUSATION**
PAMELA KALYAN, R.PH.	)	**RIGHT TO HEARING**
Certificate of Registration No. 15083	)	
	)	
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 scheduled your hearing on this matter for Wednesday, January 11, 2017, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 South Las Vegas Blvd, Las Vegas, Nevada.

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 2nd day of December, 2016.

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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 16-087-RPH-S**
	)	
Petitioner,	)	
v.	)	**ANSWER AND**
	)	**NOTICE OF DEFENSE**
PAMELA KALYAN, R.PH.	)	
Certificate of Registration No. 15083	)	
	)	
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.

_____

PAMELA KALYAN, R.PH.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JASON CAZAR, PT.** **Certificate of Registration No. PT10508** **MARK FRIEDLANDER** **Certificate of Registration No. 07517** **TONY HUFFMAN, RPH** **Certificate of Registration No. 13199** **CARDINAL HEALTH 414 LLC** **Certificate of Registration No. PHNU02921** **Respondents.** /	**CASE NOS. 16-079-PT-S** **16-079-RPH-A-S** **16-079-RPH-B-S** **16-079-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 Jason Cazar (Mr. Cazar), Certificate of Registration No. PT10508, was a registered pharmaceutical technician with the Board, Respondents Mark Friedlander (Mr. Friedlander), Certificate of Registration No. 07517, and Tony Huffman (Mr. Huffman), Certificate of Registration No. 13199, were registered pharmacists with the Board and Respondent Cardinal Health 414 LLC, Certificate of Registration No. PHNU02921 (Cardinal Health), was a pharmacy registered with the Board.

II.

On or about November 9, 2016, Mr. Cazar notified Board Staff that he failed to renew his license by the expiration date on October 31, 2016. Mr. Cazar reported that he did not

provide written notice to the Board after changing his residence and therefore did not receive his renewal notice. Mr. Cazar was able to renew his pharmaceutical technician registration after it expired, which he did on November 8, 2016.

III.

Board Staff requested Cardinal Health's staff work schedule from November 1, 2016, through November 8, 2016, from Tony Huffman, Pharmacist/Technician Supervisor. From the records provided, Board Staff ascertained that Mr. Cazar had worked at Cardinal Health for approximately five (5) days between November 1, 2016 and November 8, 2016, without a valid pharmaceutical technician registration. Mr. Huffman was unable to produce a written record showing the pharmacist(s) on duty during the period Mr. Cazar worked without a valid registration.

IV.

During the period Mr. Cazar worked without a valid registration, Mark Friedlander was the managing pharmacist at Cardinal Health. Mr. Friedlander was out on FMLA leave since October 26, 2016.

FIRST CAUSE OF ACTION

(Jason Cazar)

V.

By working at Cardinal Health 414 LLC for approximately 5 days between November 1, 2016 and November 8, 2016, when he did not have a current pharmaceutical technician registration, Jason Cazar violated Nevada Administrative Code (NAC) 639.240(1), which violations are grounds for discipline pursuant to NRS 639.210(4), and/or (13), or alternatively, under NRS 639.255.

SECOND CAUSE OF ACTION

(Mark Friedlander)

VI.

As the managing pharmacist during the period of November 1, 2016, through November 8, 2016, for the pharmacy in which Mr. Cazar worked without a license, and in failing to verify that Mr. Cazar had timely and validly renewed his registration, Mark Friedlander violated NRS 639.210(4) and/or (15) and/or NAC 639.945(1) (i), which violations are grounds for discipline pursuant to NRS 639.210(4), and/or (15), or alternatively, under NRS 639.255.

By failing to provide Board Staff with a written record, showing the pharmacists on duty during the hours of business. Mark Friedlander violated NRS 639.234(4) and NAC 639.245(1), which violations are grounds for discipline pursuant to NRS 639.210(4), and/or (15), or alternatively, under NRS 639.255.

THIRD CAUSE OF ACTION

(Tony Huffman)

VII.

As the Technician Supervisor during the period of November 1, 2016, through November 8, 2016, for the pharmacy in which Mr. Cazar worked without a license, and in failing to verify that Mr. Cazar had timely and validly renewed his registration, Tony Huffman violated NRS 639.210(4) and/or (12) and/or NAC 639.945(1) (i), which violations are grounds for discipline pursuant to NRS 639.210(4), and/or (12), or alternatively, under NRS 639.255.

FORTH CAUSE OF ACTION

(Cardinal Health 414 LLC)

VIII.

In owning and operating the pharmacy in which the violations described above occurred, Cardinal Health 414 LLC, is responsible for the violations described above, and is subject to discipline per NRS 639.210(4) and (12) and/or NAC 639.260 and 639.945(1)(i) and/or (2).

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

Signed this 2nd day of December, 2016.

Larry 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. 16-079-PT-S**
	)	
Petitioner,	)	
v.	)	**STATEMENT TO THE RESPONDENT**
	)	**NOTICE OF INTENDED ACTION**
JASON CAZAR, PT.	)	**AND ACCUSATION**
Certificate of Registration No. PT10508	)	**RIGHT TO HEARING**
	)	
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 scheduled your hearing on this matter for Wednesday, January 11, 2017, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 South Las Vegas Blvd, Las Vegas, Nevada.

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 2nd day of December 2016.

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

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 16-079-PT-S**
Petitioner,	)	
v.	)	**ANSWER AND**
	)	**NOTICE OF DEFENSE**
JASON CAZAR, PT.	)	
Certificate of Registration No. PT10508	)	
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, Jason Cazar Admit to that action. I failed to renew before my PT license expired. I failed to update the SBOP on my New address, In which I did not receive my renewal IN the mail

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 13 day of December, 2016.

JASON CAZAR, PT.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 16-079-PT-S**
	)	
Petitioner,	)	
v.	)	**ANSWER AND**
	)	**NOTICE OF DEFENSE**
JASON CAZAR, PT.	)	
Certificate of Registration No. PT10508	)	
	)	
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, Jason Cazar admit to that action. I failed to renew before my PT license expired. I failed to update the SBOP on my new address, In which I did not receive my Renewal in the mail

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 13 day of December, 2016.

JASON CAZAR, PT.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 16-079-RPH-A-S**
	)	
Petitioner,	)	
v.	)	**ANSWER AND**
	)	**NOTICE OF DEFENSE**
MARK FRIEDLANDER	)	
Certificate of Registration No. 07517	)	
	)	
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.

_____

MARK FRIEDLANDER, RPH.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 16-079-RPH-B-S**
	)	
Petitioner,	)	
v.	)	**ANSWER AND**
	)	**NOTICE OF DEFENSE**
TONY HUFFMAN, RPH	)	
Certificate of Registration No. 13199	)	
	)	
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.

_____

TONY HUFFMAN, RPH.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 16-079-PH-S**
	)	
Petitioner,	)	
v.	)	**ANSWER AND**
	)	**NOTICE OF DEFENSE**
CARDINAL HEALTH 414 LLC	)	
Certificate of Registration No. PHNU02921	)	
	)	
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.

_____
Print or Type name

_____
For CARDINAL HEALTH 414 LLC

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARC ANTHONY BARBOSE, RPH** **Certificate of Registration No. 14251, and** **WELL CARE COMPOUNDING PHARMACY** **Certificate of Registration No. PHN02869,** **Respondents.**	**CASE NOS. 16-034-RPH-S** **16-034-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

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

I.

The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and these respondents because at the time of the events alleged herein, Respondent Marc Barbose ("Mr. Barbose"), Certificate of Registration No. 14251, was a pharmacist licensed by the Board, and Respondent Well Care Compounding Pharmacy ("Well Care"), Certificate of Registration No. PHN02869, was a pharmacy licensed by the Board.

II.

Mr. Barbose was the Pharmacist in Charge at Well Care at the time of the events alleged herein.

III.

On May 2, 2016 through May 4, 2016, the Board—Investigator Dena McClish and Inspector

Luis Curras (the "Board Inspectors")—and the U.S. Food and Drug Administration ("FDA")—Investigators Eng and Penn, and Investigative Analyst Liu (the "FDA Inspectors")—conducted a joint inspection of Respondent Well Care's Las Vegas, Nevada facility. (The "Inspection"). The FDA initiated the Inspection after it received a complaint alleging that a patient suffered an infection from a sterile product compounded and dispensed by Well Care.

IV.

The FDA Inspectors recorded their observations from the Inspection in an eight-page report called an "FDA Form 483", which is dated May 12, 2016. A copy of that FDA Form 483 is attached hereto as **Exhibit A** and incorporated herein by reference.

V.

Inadequate Procedures to Prevent Microbiological Contamination of Drug Products

The FDA Inspectors' observations include:

1. Well Care did not have and/or its compounding staff did not follow written policies and procedures designed to prevent microbiological contamination of drug products that purported to be sterile. Ex. A, at p.1. The FDA Inspectors observed:

a. Well Care could not document evidence of "smoke studies under dynamic conditions to demonstrate unidirectional air flow patterns in [its] ISO 5 glovebox . . . where sterile injectable drug products are prepared." *Id.*

b. Well Care failed to correctly perform filter integrity testing for the batches of sterile injectable drugs it produced. *Id.*

c. Well Care's staff performed sterile manipulations without proper care to maintain a unidirectional airflow. *Id.*

d. Well Care's staff did not frequently disinfect gloves used in the sterile drug process. *Id.*

e. Well Care's staff did not take adequate care to prevent contact of sterile product surfaces with other non-sterile surfaces in the vicinity. *Id.*

f. Well Care's staff did not follow proper procedures for media fill testing. *Id.*

VI.

Deficient Aseptic Drug Product Processing Areas

2. Well Care's "[a]septic processing areas are deficient in that walls and ceilings are not smooth and/or hard surfaces that are easily cleanable." Ex. A, at p.2. Regarding Well Care's drug product processing areas, the FDA Inspectors and Board Inspectors observed:

a. Well Care's ISO 5 glovebox sat on a table with exposed wood-like (particle board) material that is "particle shedding difficult to clean and disinfect, and may harbor microbial contamination." *Id.*

b. Well Care has laminated particle board countertop/work bench and storage shelving in its clean room near its ISO 5 glovebox with "exposed wood-like material on the underneath sides." *Id.*

c. Gaps between the tiles in Well Care's clean room, along with unsmooth caulking where the tiles meet the walls. *Id.*

d. Well Care's staff reported that the clean room ceiling and storage shelving were not routinely cleaned. *Id.* at pp.2-3.

VII.

Flow of Compounding Process Not Designed to Prevent Contamination

3. The FDA Inspectors and Board Inspectors observed that the flow of components, drug product containers, closures, in-process materials, and drug products in Well Care's facility lack the necessary degree of sterility to compound safely. Ex. A, at p.3. As examples, the FDA Inspectors and Board Inspectors observed:

a. An instance during the inspection when Well Care Staff "mov[ed] components and materials from the non-ISO classified area and also from . . . clean room to the ISO 5 glovebox without disinfecting them." *Id.*

b. An instance where Well Care's Lab Manager "used his bare hands to open the plastic curtains and entered the . . . clean room head first" such that his "bare hands and facial skins touch[ed] the plastic curtains." *Id.*

c. An instance where an FDA Inspector observed Well Care's Lab Manager "weighing and mixing . . . non-sterile API and excipients . . . in the non-ISO classified area." *Id.*

d. Well Care's "mixing/heating block, including the dials were visibly stained, crusty, and dirty." *Id.*

VIII.

No Laboratory Testing of Drug Products Purporting to Be Sterile and Pyrogen-Free

4. The FDA Inspectors found that Well Care had little or no evidence that it had its products tested to verify their sterility and that they are pyrogen-free. Ex. A, at pp.3-4. The FDA Inspectors and Board Inspectors observed:

a. Well Care "does not routinely perform sterility and endotoxin testing on [its] sterile products." From January 1, 2016 through May 12, 2016, the date of the FDA Inspection, Well Care performed endotoxin testing on only eight of 270 lots of sterile product it produced. *Id.*

b. The eight tests Well Care had performed from January 1, 2016 through May 12, 2016, were "not compliant to compendial standards because 'suitability of the method for the product has not been documented.'" *Id.*

c. Well Care produced no evidence of sterility, endotoxin, or potency testing for "combination products" it produced from other Well Care produced sterile products. *Id.*

d. Well Care conducted "potency testing on one out of 270 lots of sterile product produced since January 1, 2016." *Id.*

IX.

Deficient Monitoring of Environmental Conditions in Aseptic Processing Areas

5. Well Care's "[a]septic processing areas are deficient regarding the system for monitoring environmental conditions." Ex. A, at p.4. The FDA Inspectors recorded in the FDA 483 Form:

a. Well Care did not monitor the pressure differential (PD) of the clean room. Specifically, the FDA Inspectors observed that Well Care "lacks documented evidence that the PD is monitored on each day a batch of sterile drug is prepared in the ISO 5." *Id.*

b. Well Care "has no pressure gauge installed to monitor the PD between the . . . clean room and the unclassified area." *Id.*

c. Well Care did not perform "environmental and personnel monitoring . . . [on] each day a batch of sterile drug is produced in the ISO 5 glovebox." Rather, it performed those tests "on a semi-annual basis." *Id.*

d. Well Care had no "written description, or justifications for how each environmental monitoring location was determined." *Id.*

e. Well Care did not perform growth promotion testing "for each lot of ready-to-use EnviroTest™ Media Paddles for surface and gloved fingertip sampling." *Id.*

f. Well Care failed to use media "suitable for the detection of yeast and mold species" when monitoring the environment and personnel in its clean room facility. *Id.*

X.

Deficient Cleaning and Disinfecting to Produce Aseptic Conditions in Aseptic Processing Areas

6. Well Care's processing areas are deficient and inadequate for "cleaning and disinfecting the room and equipment to produce aseptic conditions." Ex. A, at p.5. The FDA Inspectors wrote in the FDA Form 483:

a. Well Care uses "[n]on-sterile lint-free wipes and non-sterile disinfectants, specifically non-sterile Sporocidin and non-sterile Decon-Quat 200C," to clean its clean room facility and ISO 5 glovebox. *Id.*

b. Well Care did not follow its cleaning product manufacturers' "disinfectant contact time" recommendations. Specifically, the manufacturer labels for Sporocidin and Decon-Quat 200C direct users to "allow treated surfaces to remain wet for 10 minutes." The Decon-Spore 200 Plus label directs "that the contact dwell time is 6 hours at 20°C." Well Care's Lab Manager informed the FDA Inspectors that Well Care allowed only "2 to 4 minutes contact time" for each of those disinfectants. *Id.*

c. On May 2, 2016, the FDA Inspectors and Board Inspectors "observed reddish/orange spots on the interior surface of the ISO 5 glovebox main chamber viewing windows near the glovebox work bench." The Lab Manager opined that the spots were "probably spills from stopping or capping methylcobalamin (B12) vials." *Id.*

d. On the same day, the FDA Inspectors observed "an oily film covering most of the lower half interior surfaces of the ISO 5 glovebox viewing windows" and "white crystal-like structures along the lower edge interior surfaces of the viewing windows near the glovebox work bench." The Lab Manager stated that "oil and white crystal-like structures were probably from sterile filter explosions and they have been there for about a year." *Id.*

e. On May 4, 2016, the FDA Inspectors observed Well Care's Lab Manager "performing daily cleaning of the ISO 5 glovebox using sterile 70% IPA and non-sterile wipes." During that cleaning, the Lab Manager "could not reach all interior surfaces of the glovebox because the gauntlet gloves were not long enough." *Id.*

f. The FDA Inspector further observed the Lab Manager "cleaning the glovebox antechamber with his upper body leaning inside the chamber." The Lab Manager did so wearing a "non-sterile gown, non-sterile hairnet, and non-sterile beard cover. The bare skin on his face was exposed." *Id.*

g. The same day (May 4, 2016), the FDA Inspectors observed "stains on the plastic curtains next to the ISO 5 glovebox . . . on the lower half sections of the curtains close to the floor." The Lab Manager "confirmed" on May 10, 2016, that the stains "were on both sides of the

curtains and were from mopping and splashing of the floor cleaning agents." Well Care had no documentation to show that the curtains have been cleaned. Ex. A, at pp. 5-6.

h. During the FDA's inspection of Well Care's clean room facility, the FDA Inspectors "observed a yellowish debris-like material on the ISO 5 glovebox main chamber HEPA filter housing." Well Care's Lab Manager opined that the debris was likely due to a filter explosion. *Id.*

i. Well Care could provide to the FDA Inspectors "no documented evidence that the cleaning and disinfecting of the clean room facility [had] been performed daily and weekly as required." At the time, Well Care could provide cleaning logs for February, March, and May of 2016, but no others. *Id.*

XI.

Unsupported Beyond-Use Dates for Sterile Products

7. During the Inspection, the FDA Inspectors and Board Inspectors observed that Well Care assigned improper Beyond-Use Dates (BUDs) to its sterile products.

a. During their investigation, the FDA Investigators determined that Well Care "routinely assigns Beyond-Use Dates that are longer than the expiration dates of the ingredients" without justification for assigning extended expiration dates. *Id.* Ex. A, at p. 6.

b. As an example, the FDA Inspectors cited "ESTRODIOL VALERATE, Lot #03092016@19 [with] a Beyond-Use Date of 06/07/2016. This lot was prepared using Grapeseed Oil Lot # 107414/B which had an expiration date of 02/28/2016." The BUD for Well Care's product was over ninety days after the grapeseed oil used to produce that product expired. *Id.*

c. The FDA Inspector found that "8 of 10 lots reviewed of HCG Injection Solution which were produced in the last 6 months [prior to the inspection] contained ingredients that expired before the finished products Beyond-Use Date. 4 of 8 lots of Estradiol Valerate 19 mg/ML Injection Solution which were produced in the last 6 months contained ingredients that expired before the finished product's Beyond-Use Date." *Id.*

d. Well Care's testing program for its sterile products consists of only testing for potency. The program does not include testing for sterility or endotoxin testing. *Id.*

e. Well Care has no written procedure for its BUD testing program. *Id.*

f. Well Care marketed it products for multi-dose use without studies to support that its container closure systems provided adequate protection for multi-dose use. *Id.*

8. The Board Inspectors also observed Well Care assigning improper extended BUDs without proof of appropriate testing or published data to support those dates.

9. The Board Inspectors likewise observed Well Care assigning extended BUDs that were beyond the expiration date of their ingredients without proof of appropriate testing or published data to support those dates.

XII.

Inadequate Cleaning and Sterilization of Drug Product Containers and Closures

10. Well Care's drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for the intended use. Ex. A, at p. 7.

11. Th FDA Inspectors wrote:

> Specifically, glassware used in the mixing and heating of API for sterile drug processing is not adequately depyrogenated. We observed glassware was depyrogenated in a dry heat oven at 50°C for 20 to 25 minutes. Your firm's SOP 8.010, entitled, "Sterilization and Depyrogenation", version 1.0, effective 08/26/2013, section 9.6.2 specifies exposure time of 250°C for two hours in order to achieve depyrogenation.

Id.

XIII.

No Policies, Procedures or Program to Review Product Discrepancies and Failures

12. Well Care does not have a program in place to review any discrepancy and the failure of any batch of its sterile products. As examples, the FDA Inspectors stated in their report:

> [Well Care] has experienced failed batches due to aseptic filter failures.

> The Lab Manager explained that the failures occur approximately every 4 to 5 months. The batch failures were not investigated. The Lab Manager stated that the batch records were destroyed. However, there is no documented evidence showing that the batches were discarded.
>
> On 05/02/2016 and 05/04/2016, we observed the aseptic preparations of TESTOSTERONE CYP # 04292016:35@11 and METHYLCOBALAMIN Lot # 05042016:98@11. We observed a failure in the bubble point test for the aseptic filter during the production of sterile product. No investigation was performed on the failed bubble point test.

Ex. A at p.7.

XIV.

13. During the Inspection, the Board Inspectors also observed and gathered evidence that Well Care pre-prints purported results of bubble point/filter integrity tests on its compounding worksheets when those tests were never performed. The recorded results were false.

XV.

Failure to Perform Routine Equipment Calibration

14. Well Care did not perform routine calibration of its sterile compounding equipment to assure proper performance. During the Inspection, the FDA Inspectors and Board Inspectors observed:

> Specifically, there is a lack of equipment calibration. For example, [Well Care] has not calibrated the following equipment/instruments.
>
> - Pressure gauges for the ISO 5 glovebox have never been calibrated.
> - Pressure gauges for the bubble point/filter integrity test have never been calibrated.
> - Incubator used for the incubation of environmental monitoring (EM), personal monitoring (PM) and media fills (MF) tests have never been calibrated.
> - The Portable hand held PH meter is calibrated every 6 month[s] with no log record of calibrations.

- Thermometers and probes for the refrigerator and freezer used in the storage of quarantine and released finished sterile drug products have never been calibrated.

Ex. A at p.7.

XVI.

Inadequate Apparel to Protect Drug Products from Contamination

15. Well Care employees do not wear the protective apparel necessary to protect drug products from contamination. Ex. A at p.8.

16. The FDA Inspectors noted in the FDA Form 483 that "the garments and protective apparel worn by [Well Care's] Lab Manager is inadequate. [Well Care's] clean room gowning consists of non-sterile shoe covers, non-sterile hair net, non-sterile face mask, non-sterile beard cover, non-sterile lab coat, and sterile gloves." *Id.*

17. While accompanying the FDA Inspectors, the Board Inspectors also observed Well Care staff compounding without proper gowning. They observed Well Care staff working without appropriate personal protective equipment. For example, they noted Well Care technicians working on numerous occasions during the FDA Inspection compounding hormones without facial protection. *Id.*

XVII.

18. While accompanying the FDA Inspectors, the Board Inspectors found evidence that Well Care routinely compounds and sells products to practitioners for office use when there was no evidence or indication that those sales were necessary to for emergency medical reasons. Those significant sales as a matter of course constitute wholesaling, for which Well Care does not have a license.

XVIII.

19. The Board Inspectors observed that Well Care staff, and particularly Lab Manager/Pharmaceutical Technician Nicholas Manganiello did not demonstrate competency and

efficiency in compounding sterile products. Like the FDA Inspectors, the Board Inspectors observed that Mr. Manganiello has not received the training necessary to be competent and proficient at sterile compounding.

XIX.

20. The Board Inspectors observed that Well Care's compounded product labels are deficient in that, at a minimum, they fail to state the name and concentration of each active ingredient in each product.

XX.

21. During the Inspection, the Board's Inspectors observed Well Care operating outside of the 3 to 1 pharmaceutical technician to pharmacist ratio for approximately 2 to 3 hours each day.

22. The Board Investigator observed the technicians engaged in the duties that limited by law to pharmaceutical technicians during those times. Well Care provided documents to support that conclusion.

XXI.

23. The Board Inspectors also found a partially consumed and expired phentermine lollipop in the drawer of Lab Manager Manganiello. No respondent could produce a prescription for that medication

XXII.

24. During the Inspection, the Board Inspectors observed Well Care staff using ductless fume hoods in its hazardous and non-sterile preparation areas without turning those hoods on.

XXIII.

25. On or about May 10, 2016, Well Care's Chief Operating Officer, Marcelino Casal, sent a letter to the Board indicating that it would voluntarily recall all of its sterile compounded products produced from January 1, 2016 to May 2, 2016. Mr. Casal also indicated that Well Care would cease compounding sterile products immediately.

XXIV.

FIRST CAUSE OF ACTION
Deficient Physical Environment
(All Respondents)

By failing to maintain an aseptic processing area, and by compounding sterile products in an area that is physically inadequate for the purposes of sterile compounding, including not-easily cleanable and impermeable surfaces on walls, ceilings, shelves, tables and equipment, as described herein, Respondents, and each of them, violated NAC 639.6705 and/or NAC 639.945(1)(i), which violations are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXV.

SECOND CAUSE OF ACTION
Inadequate Protective Apparel
(All Respondents)

By failing to establish, maintain and follow written policies and procedures designed to ensure that all Well Care staff members working in Well Care's sterile compounding areas wear adequate and appropriate garments and protective apparel, including sterile shoe covers, hair net, face mask, beard cover, lab coat, and gloves, Respondents, and each of them, violated NAC 639.6705, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXVI.

THIRD CAUSE OF ACTION
Deficient Cleaning Processes
(All Respondents)

By failing to establish, maintain and follow written policies and procedures to ensure clean and sterilized drug product containers, as noted by the FDA Inspectors, Respondents, and each of them, violated NAC 639.6701 and/or NAC 639.67069, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXVII.

FOURTH CAUSE OF ACTION
Deficient Equipment Calibration and Maintenance
(All Respondents)

By failing to establish, maintain and follow written policies and procedures designed to adequately inspect, clean and maintain the equipment, components, closures, labels and other materials Well Care used in its process for compounding its sterile drug product, Respondents, and each of them, violated NAC 639.6701 and/or NAC 639.67015, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXVIII.

FIFTH CAUSE OF ACTION
Deficient Testing and Monitoring of Physical Environment
(All Respondents)

In failing to establish, maintain and follow written policies and procedures designed to require testing, monitoring and maintaining records of the testing and monitoring of the air in each of its controlled environments to ensure that they attain the air quality required by the provisions of NAC 639.661 to 639.690, Respondents, and each of them, violated NAC 639.67015 and/or NAC 639.67051, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXIX.

SIXTH CAUSE OF ACTION
Deficient Product Monitoring
(All Respondents)

In failing to establish, maintain and follow written policies and procedures for batch testing of high-risk sterile compounded drug products and "monitoring each final compounded drug product and validating the compounding processes that may be responsible for causing variability in [its] compounded drug product[s]", Respondents, and each of them, violated NAC 639.67015 and or NAC

639.67071, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXX.

SEVENTH CAUSE OF ACTION
Deficient Staff Training
(All Respondents)

In failing to establish, maintain and follow written policies and procedures designed to ensure that each pharmacist and pharmaceutical technician engaged in the practice of compounding drug products was competent, proficient and compliant with NAC 639.661 to 639.690 and its internal policies and procedures for compounding the compounded drug products Well Care compounded, and in failing to ensure that its pharmacists and pharmaceutical technicians received sufficient and ongoing training to maintain proficiency and compliancy, Respondents, and each of them, violated NAC 639.67013 and/or NAC 639.67053, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXXI.

EIGHTH CAUSE OF ACTION
Failure to Keep Accurate Records
(All Respondents)

In failing to make adequate and accurate records of its sterile compounding activities, as required by NAC 639.6701, NAC 639.6702, and NAC 639.67055, and in failing to maintain those records, as required by NAC 639.67019, Respondents, and each of them, violated each of those regulations, as described herein, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXXII.

NINTH CAUSE OF ACTION

Beyond-Use Dating

(All Respondents)

By dispensing compounded medications with Beyond-Use Dates assigned to them that exceed the Beyond-Use Dates of the individual ingredients of those compounded medications and without written proof of appropriate testing or published data indicating that the drug was safe and effective through the extended Beyond-Use Dates that Well Care assigned, Respondents, and each of them, violated NAC 639.6702 and/or NAC 639.67067, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXXIII.

TENTH CAUSE OF ACTION

Inadequate Labeling

(All Respondents)

By dispensing compounded medications without labels showing the name of each active ingredient in the compound and the concentration of each, Respondents, and each of them, violated NAC 639.680, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11), (12) and/or (15), as well as NRS 639.255.

XXXIV.

ELEVENTH CAUSE OF ACTION

Pharmacy Technician Ratio

(Respondent Well Care and Barbose)

By dispensing medication at times when the pharmacist on duty was supervising four or more pharmaceutical technicians at one time, Respondent Barbose violated NAC 639.250, which violations constitute unprofessional conduct per NAC 639.945(1)(i), and are grounds for action pursuant to NRS 639.210(4), (11) and/or (15), as well as NRS 639.255.

XXXV.

TWELVTH CAUSE OF ACTION
Managing Pharmacist Responsibilities
(Respondent Marc Barbose)

As a managing pharmacist who knew of and allowed the foregoing violations, or any one of them, to occur in his pharmacy, Respondent Mr. Barbose 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.

XXXVI.

THIRTEENTH CAUSE OF ACTION
Pharmacy Responsibility
(Well Care Compounding Pharmacy)

As the pharmacy in which the violations alleged above occurred, Well Care Compounding Pharmacy is statutorily responsible for the actions of Respondents 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 December, 2016.

J. David Wuest, Deputy Executive Secretary
Nevada State Board of Pharmacy on behalf of
Larry L. Pinson, Executive Secretary

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,	)	**STATEMENT TO THE RESPONDENT**
	)	**NOTICE OF INTENDED ACTION**
Petitioner,	)	**AND ACCUSATION**
v.	)	**RIGHT TO HEARING**
	)	
MARC ANTHONY BARBOSE, RPH	)	**CASE NO. 16-034-RPH-S**
Certificate of Registration No. 14251	)	
	)	
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 scheduled your hearing on this matter for Wednesday, January 11, 2017, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

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 December, 2016.

J. David Wuest, Deputy Executive Secretary
Nevada State Board of Pharmacy on behalf of
Larry L. Pinson, Executive Secretary

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**ANSWER AND**
	)	**NOTICE OF DEFENSE**
Petitioner,	)	
v.	)	
	)	
MARC ANTHONY BARBOSE, RPH	)	**CASE NO. 16-034-RPH-S**
Certificate of Registration No. 14251	)	
	)	
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, 2016.

_____

MARC BARBOSE, R.PH.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**ANSWER AND**
	)	**NOTICE OF DEFENSE**
Petitioner,	)	
v.	)	
	)	
WELL CARE COMPOUNDING PHARMACY	)	**CASE NO. 16-034-PH-S**
Certificate of Registration No. PHC02590	)	
	)	
Respondent.	/	

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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, 2016.

_____

Type or print name

_____

AUTHORIZED REPRESENTATIVE FOR
WELL CARE COMPOUNDING PHARMACY