

MAR 14 2017

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD
OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JESSICA NGUYEN, RPH

Certificate of Registration No. 15397

MARTIN O. CHIBUEZE, RPH

Certificate of Registration No. 17555

SPRING VALLEY PHARMACY

Certificate of Registration No. PH02375

Respondents.

CASE NO. 16-015-RPH-A-S

16-015-RPH-B-S

16-015-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.

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 Jessica Nguyen (Ms. Nguyen), Certificate of Registration No. 15397, and Respondent Martin O. Chibueze (Mr. Chibueze), Certificate of Registration No. 17555, were pharmacists licensed by the Board, and Respondent Spring Valley Pharmacy (Spring Valley), Certificate of Registration No. PH02375, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

II.

On or about February 5, 2016, L.T. saw APRN, M.G. at the Mind Body Solutions Clinic. M.G. prescribed a quantity of #120 Adderall 10 mg. tablets with instructions to take one tablet four times daily.

III.

L.T. tendered the prescription to Spring Valley the day she received it. Spring Valley assigned it Prescription No. 26542 and dispensed the medication the same day.

IV.

Later that evening, L.T. opened the medication bottle and discovered that it contained only thirty (30) tablets of Adderall, instead of the one-hundred and twenty (120) tablets as prescribed.

V.

L.T. contacted Spring Valley to report the Adderall shortage.

VI.

Pharmacist Martin Chibueze at Spring Valley informed L.T. that he checked the pharmacy's Adderall 10 mg. tablet inventory and he found no discrepancies. He also said that he would view the video of L.T.'s prescription being filled.

VII.

In a written statement, Mr. Chibueze states that he conducted a physical count of Spring Valley's Adderall 10 mg. tablets and found no discrepancies.

VIII.

He also stated that Spring Valley's video system overrides recorded video every forty-eight hours, so he was not able to view the filling of L.T.'s prescription.

IX.

When L.T. was unable to resolve the medication shortage with Spring Valley, she reported the incident to law enforcement and filed a police report.

X.

During Board Staff's investigation of Prescription No. 26542 and L.T.'s complaint, the Board Investigator discovered that Spring Valley's pharmacy workflow software does not depict the required data elements of a lawful prescription.

XI.

The Board Investigator found substantial discrepancies in Spring Valley's electronic Schedule II perpetual inventory recordkeeping. For example:

1. Amphetamine Salts 10 mg NDC 00555-0972-02: Prescription No. 26542 appears on this inventory four times, once on February 5, 2016, and three times on February 8. Two of those entries show that Spring Valley dispensed the medication, and two show that Spring Valley added the same amount (120 tablets) back into its inventory. The inventory showed that Spring Valley should have had 86 tablets in its inventory on March 15, 2016. The Board Investigator conducted a count of the Amphetamine Salts 10 mg tablets on March 15, 2016, and counted 94.

2. Amphetamine 10 mg ER, NDC 000555-07870-2: Prescription No. 26542 appears on this inventory twice. It shows that Spring Valley dispensed 120 tablets on February 8, 2016, and then received the same amount back into its inventory. The inventory showed that Spring Valley should have had 195 tablets in its inventory on March 15, 2016. The Board Investigator counted and documented 215 tablets.

3. Amphetamine 10 mg NDC 45963-0745-11: Prescription No. 26542 appears on this inventory once, when Spring Valley purportedly dispensed 120 tablets. The inventory shows that Spring Valley should have had count of -75 tablets. The Board Investigator counted 23 tablets.

XII.

According to Spring Valley's workflow records for Prescription No. 26542, pharmaceutical technician Rolando (Mr. Urrutia) entered the prescription data.

XIII.

Spring Valley provided the Board Investigator a copy of the workflow screen, "Rx's Checked", for Prescription No. 26542, on March 15, 2016. The record failed to capture the fill technician, verifying pharmacist, prescription verification date/time, counseling pharmacist, and counseling date/time.

XIV.

On March 24, 2016, Spring Valley provided a second copy of the "Rx's Checked" record for Prescription No. 26542. That copy was identical to the March 15th copy except for an additional entry, "Martin Chibueze", in data field "IOU Pharmacist".¹

XV.

The information in Spring Valley's records reflect an inconsistency as to the NDC for Prescription No. 26542. The NDC on L.T.'s patient profile is 45963-0745-11. The NDC on the label of the bottle dispensed to L.T. is 00555-0972-02.

XVI.

The label on the bottle did not include an expiration date for the medication.

XVII.

Spring Valley's electronic perpetual inventories on March 15, 2016, showed an inventory of negative counts for Amphetamine 10 mg. tablets. Those negative counts were not consistent with the Board Inspector's physical counts of that medication at the pharmacy.

XVIII.

Spring Valley's records do not accurately show who was working at the time the pharmacy filled Prescription No. 26542. Respondent Ms. Nguyen purportedly worked from 8:00 AM until 12:00 PM, which includes the time the pharmacy filled Prescription No. 26542. The

¹ "IOU" indicates a remaining medication fill from a prior partial fill.

pharmacy's Time Clock Report does not reflect that Ms. Nguyen worked in the pharmacy during those times.

XIX.

At the time Spring Valley filled Prescription No. 26542, pharmaceutical technician Rolando Urrutia worked at the pharmacy and participated in at least the data entry process. Urrutia left Spring Valley at short time later. Spring Valley and Ms. Nguyen failed to report Mr. Urrutia's employment with and termination from the pharmacy.

XX.

Pharmacy records show that Mr. Chibueze verified Prescription No. 26542 and sold the medication to L.T. There is no record that he provided counseling, and L.T. reported that she did not receive counseling for that prescription. Spring Valley could not initially provide a counseling log for the prescription. Ms. Nguyen later faxed over a duplicate of the patient's signature with the words "Counseling Log" handwritten in the margin.

XXI.

In the absence of critical records, the Board Investigator was unable to reliably determine whether Spring Valley accurately filled Prescription No. 26542.

FIRST CAUSE OF ACTION
(Spring Valley Pharmacy)

XXII.

NAC 639.930(3) and (4) require a computerized system in a pharmacy to make a record of each modification or manipulation of the information of each prescription in the system. NAC 639.935(g)(3) and (4) likewise require a pharmacy's computerized system have the capability to print "[t]he history of each prescription filled by the pharmacy, including, without limitation, a record of each [m]odification or manipulation of information concerning the prescription; and . . . [o]ther act related to the processing, filling or dispensing of the prescription."

XXIII.

NAC 639.751 requires a pharmacy's computer system to accurately capture the signature, initials or name of the pharmacist or technician who participates in each step of the filling process of a prescription.

XXIV.

Spring Valley Pharmacy's computer system does not accurately capture and retain the information required by NAC 639.751, NAC 639.930(3) and (4), and NAC 639.935(g), as demonstrated by the system's failure to capture, retain, and print the required information for Prescription No. 26542. Spring Valley Pharmacy therefore violated each of those regulations and is subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

SECOND CAUSE OF ACTION

(Spring Valley Pharmacy)

XXV.

NAC 639.751(1)(b) and (2), and NAC 639.930(3) require a pharmacy computer system to have adequate safeguards to identify whether information in the system concerning a prescription has been modified or manipulated, and, where information was modified or manipulated, identify the manner, date and person who modified or manipulated the information. NAC 639.930(4) and (5) requires the pharmacy's computer system to maintain the information identified per NAC 639.930(3) and to prevent the removal of that information and the record of a prescription once the system assigns a number to the prescription.

XXVI.

By failing to maintain adequate safeguards in its computer system to identify the information required by NAC 639.751(1)(b) and (2) and NAC 639.930(3) as to Prescription No. 26542, and by failing to prevent the removal of that information as required by NAC 639.930(4)

and (5), Spring Valley violated each of those regulations and is subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

THIRD CAUSE OF ACTION

(Spring Valley Pharmacy)

XXVII.

NRS 639.2801 requires all prescriptions to be dispensed in a container with a label affixed stating, among other things, the date, the manufacturer name or NDC number, the expiration date or BUD, the strength/concentration of the drug, certain warning labels and the directions for use.

XXVIII.

By failing to properly label the container for Prescription No. 26542 to include the accurate manufacturer name or NDC number, or expiration date, Spring Valley violated NRS 639.2801 and is subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

FOURTH CAUSE OF ACTION

(Spring Valley Pharmacy)

XXIX.

“Performing or in any way being a party to any fraudulent or deceitful practice or transaction” constitutes “unprofessional conduct and conduct contrary to the public interest.” NAC 639.945(1)(h). Engaging in conduct that constitutes unprofessional conduct or that is contrary to the public interest is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

XXX.

Additionally, “[a] drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular.” NRS 585.410. “The manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded” is prohibited in the State of Nevada. NRS 585.520.

XXXI.

By placing the NDC 00555-0972-02 on the label of the bottle it dispensed to L.T., and recording a different NDC (45963-0745-11) in L.T.'s patient profile, Spring Valley engaged in unprofessional conduct and violated NRS 585.520. It is therefore subject to discipline pursuant to NRS 639.210(4) and/or (12), as well as NRS 639.255.

FIFTH CAUSE OF ACTION

(Spring Valley Pharmacy)

XXXII.

NAC 639.485(1) requires each pharmacy to maintain records of the receipt, distribution and destruction of all controlled substance handled by the pharmacy. NAC 639.485(2) requires that each "pharmacy shall maintain a perpetual inventory of any controlled substance listed in schedule II." *See also* NRS 453.246 (requiring pharmacies to "keep records and maintain inventories" in conformance with the record keeping and inventory requirements of state and federal law).

XXXIII.

Spring Valley violated those statutes and regulations by failing to maintain an accurate perpetual inventory of its schedule II controlled substances, in particular Amphetamine Salts, Amphetamine 10 mg ER and Amphetamine 10 mg, as alleged herein. The pharmacy's inventory records on March 15, 2016, showed negative numbers of each of those substances, which also did not conform with the Board Investigator's physical account of those substances, and which the pharmacy staff could not explain. Additionally, Prescription No. 26542 appeared on three separate Spring Valley inventories.

SIXTH CAUSE OF ACTION

(Spring Valley Pharmacy)

XXXIV.

NAC 639.245 requires that for each pharmacy, “[a] written record must be kept available for inspection showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business.” By failing to keep a written record that reflects when Ms. Nguyen is on duty at Spring Valley Pharmacy, Spring Valley Pharmacy violated that regulation and is therefore subject to discipline pursuant to NRS 639.210(4) and/or (12), as well as NRS 639.255.

SEVENTH CAUSE OF ACTION
(Spring Valley Pharmacy)

XXXV.

NAC 639.540 requires the owner, manager or operator of a pharmacy to, “within 10 days after the employment or termination of employment of a registered pharmacist, intern pharmacist, pharmaceutical technician or pharmaceutical technician in training, give written notice to the Executive Secretary of that employment or termination. The notice must include the name, residential address and certificate number of the employee or former employee.”

By failing to give the Board written notice of pharmaceutical technician Roland Urrutia’s employment and subsequent termination, Spring Valley Pharmacy violated that regulation and is therefore subject to discipline pursuant to NRS 639.210(4) and/or (12), as well as NRS 639.255.

EIGHTH CAUSE OF ACTION
(Martin Chibueze)

XXXVI.

NRS 639.266(1) requires a pharmacist to “communicate matters which will enhance therapy through drugs with the patient or a person caring for the patient.” NAC 639.707(1) and (2) further require counseling for all new prescriptions and provide a list of elements to be included as part of proper counseling. Additionally, NAC 639.707(6) requires the pharmacist to create a record that counseling was either refused or occurred.

XXXVII.

Here, there is no record that Mr. Chibueze provided adequate counseling to L.T. By failing to provide counseling for L.T.'s new prescription, and to create some documentation regarding whether counseling occurred, Mr. Chibueze violated NRS 639.266(1), NAC 639.707(1), (2) and (6), as well as NAC 639.945(1)(i), which violations are grounds for action pursuant to NRS 639.210(4), (11) and/or (12), and under NRS 639.255.

NINTH CAUSE OF ACTION
(Spring Valley Pharmacy)

XXXVIII.

NAC 639.707(6) requires a pharmacist to create a record at the time a medication is dispensed to indicate whether counseling occurred or was refused by the patient. NAC 639.751(1)(b) and (2), and NAC 639.930(3) require a pharmacy computer system to have adequate safeguards to identify whether information in the system concerning a prescription has been modified or manipulated, and, where information was modified or manipulated, identify the manner, date and person who modified or manipulated the information. Additionally, NAC 639.930(4) and (5) requires the pharmacy's computer system to maintain the information identified per NAC 639.930(3) and to prevent the removal of that information and the record of a prescription once the system assigns a number to the prescription.

XXXIX.

Here, Spring Valley's computer system failed to create and retain a record of whether Mr. Chibueze provided counseling to L.T. Thus, Spring Valley violated NAC 639.707(6) and/or NAC 639.930(3), (4) and/or (5), which violations are grounds for action pursuant to NRS 639.210(4), (11) and/or (12), and under NRS 639.255.

TENTH CAUSE OF ACTION

(Jessica Nguyen)

XL.

As the managing pharmacist/pharmacist in charge of Spring Valley at the time of each of the violations alleged herein, Respondent Ms. Nguyen is responsible for those violations, including those of her employees. *See* NRS 639.0087, NRS 639.210(15), NRS 639.220(3)(c), NAC 639.510(2), NAC 639.702; and NAC 639.910(2). Ms. Nguyen's pharmacist license, Certificate of Registration No. 15397, is therefore subject to discipline, suspension, or revocation pursuant to those statutes and regulations, NRS 639.210(4), (9), (11) - (12), (15) and/or (17), as well as NRS 639.230(5) and/or NRS 639.255.

ELEVENTH CAUSE OF ACTION

(Spring Valley Pharmacy and Jessica Nguyen)


XLI.

As the pharmacy and owner of the pharmacy in which the violations alleged herein occurred, Respondents Spring Valley and Ms. Nguyen, respectively, are each responsible for the violations set forth above pursuant to NAC 639.702 and NAC 639.945(2). Each of their licenses, Certificate of Registration No. 15397 (Ms. Nguyen), and Certificate of Registration No. PH02375 (Spring Valley) are therefore subject to discipline pursuant to NRS 639.210(4), (9), (11) - (12), (15) and/or (17), as well as NRS 639.230(5) and/or NRS 639.255.

XLII.

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.

DATED this 14 day of March 2017.



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,

Petitioner,

v.

JESSICA NGUYEN, RPH

Certificate of Registration No. 15397

Respondent.

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

CASE NO. 16-015-RPH-A-S

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 Thursday, April 13, 2017, at 9:00 a.m., or soon thereafter, 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 14th day of March 2017.



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

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 2017.

JESSICA NGUYEN, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,)	ANSWER AND
)	NOTICE OF DEFENSE
Petitioner,)	
v.)	
)	CASE NO. 16-015-RPH-B-S
MARTIN O. CHIBUEZE, RPH)	
Certificate of Registration No. 17555,)	
)	
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 2017.

MARTIN O. CHIBUEZE, RPH

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 2017.

Type or print name

AUTHORIZED REPRESENTATIVE FOR
SPRING VALLEY PHARMACY

FILED

MAR 14 2017

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JESSICA NGUYEN, RPH

Certificate of Registration No. 15397, and

SPRING VALLEY PHARMACY

Certificate of Registration No. PH02375

Respondents.

CASE NO. 16-022-RPH-S

16-022-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.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over these matters and these Respondents because at the time of the alleged events, Respondent Jessica Nguyen (Ms. Nguyen), Certificate of Registration No. 15397, was a pharmacist licensed by the Board, and Respondent Spring Valley Pharmacy (Spring Valley), Certificate of Registration No. PH02375, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

II.

This case involves three prescriptions for one-year-old patient A.G. One prescription for Methotrexate compounded liquid, with refills, designated as Prescription No. 676992, and two prescriptions for Flagyl suspension, designated Prescription Nos. 675133 and 678825.

III.

In March 2016, a Board Inspector conducted Spring Valley's annual pharmacy inspection.

IV.

The Board Inspector observed four (4) vials of Methotrexate 250mg/10ml injection on the pharmacy shelf and requested to see the prescription and records related to the drug.

V.

The pharmacy manager, Respondent Ms. Nguyen, presented the prescription, Prescription No. 676992, and all available records to the Board Inspector.

VI.

The Board Inspector observed:

1. A.G.'s physician transmitted what would become Prescription No. 676992 to Spring Valley electronically on February 23, 2016.
2. Spring Valley's computer system shows that Ms. Nguyen entered the prescription data into the computer.
3. The system did not capture the signature, initials, or the name of each pharmacist or pharmaceutical technician who played a role in processing or filling Prescription No. 676992.
4. The computer system also failed to record which pharmacist verified the medication as accurate before dispensing it.

VII.

In April 2016, Ms. Nguyen provided the Board Inspector a duplicate label for Prescription No. 676992. The duplicate label shows that Spring Valley dispensed the prescription initially on February 23, 2016, with the instructions: "GIVE 0.4 ML BY MOUTH EVERY WEEK ON MONDAY (25MG/ML)." (Emphasis added.)

VIII.

Ms. Nguyen also provided the Board Inspector a copy of the prescription from the pharmacy's archived paper records. That copy included the back label from the February 23, 2016 initial fill. That copy of the back label did not match the duplicate label Ms. Nguyen provided to the Board Inspectors. The instructions on that copy of the back label are: "GIVE 4ML BY MOUTH EVERY WEEK ON MONDAY (GIVE 25MG/10ML)."³ (Emphasis added.)

IX.

The instructions on the duplicate label and on the back label should match. Ms. Nguyen could not explain why the records she provided were inconsistent.

X.

Patient A.G.'s grandmother and caregiver (Ms. Smith) later recalled that the bottle of Methotrexate Spring Valley dispensed on February 23, 2016—the initial fill—was a 2 mL bottle of liquid. The label on the bottle included the direction to give 4mL, rather than 0.4 mL. Ms. Smith is a registered pharmaceutical technician and is therefore familiar with prescription bottle sizes, dosages and labeling.

XI.

Due to an adjustment by A.G.'s grandmother, A.G. reportedly ingested the correct dosage and experienced no adverse effects from the incident.

XII.

A.G.'s physician sent Spring Valley a clarified prescription on March 15, 2016 for a 20 count of "Methotrexate 2.5 MG Oral Tablet." The SIG for the prescription was "10 Milligram (25mg/10ml) Milligram, Oral 4ml once a week on Monday." (Emphasis added.) The notes to the pharmacist similarly stated: "Compound to Methotrexate 25mg/10ml every Monday." The prescription allowed for six refills. (Emphasis added.)

XIII.

Spring Valley was unable to produce any record of this e-prescription. The Board Inspector obtained a copy from A.G.'s physician.

XIV.

The label on the bottle that Spring Valley dispensed pursuant to that clarified prescription, which Spring Valley continued to designate as Prescription No. 676992, has instructions to "GIVE 0.4 ML BY MOUTH EVERY WEEK ON MONDAY (25MG/ML). (Emphasis added.) That label failed to include: (1) the medication's strength/concentration, or (2) the required warning labels.

XV.

Spring Valley's records show that Respondent Ms. Nguyen input the prescription data in Spring Valley's computer system. They also show that Ms. Nguyen verified the medication before the pharmacy dispensed it.

XVI.

Spring Valley could not produce records to show who processed the prescription and filled the medication.

XVII.

Spring Valley could not produce evidence to show that anyone contacted A.G.'s physician for approval to change the compound from "(25mg/10ml) Milligram, Oral 4ml once a week on Monday" to "GIVE 0.4 ML BY MOUTH EVERY WEEK ON MONDAY (25MG/ML)."

XVIII.

Both the duplicate labels for Prescription No. 676992 for fill dates February 23, 2017 and refill date March 15, 2016, show Mylan as the medication manufacturer. The NDC on the labels

is 51079-0670-05. Neither Mylan nor that NDC number appears on any invoice for Methotrexate purchased by Spring Valley.

XIX.

Respondent Ms. Nguyen verbally admitted to the Board Investigator that she changed the NDC numbers on medications in Spring Valley's system so that they would qualify for payment by insurance companies.

XX.

The Board investigator requested a copy of Spring Valley's billing records for the medications dispensed for A.G. Neither Respondent Spring Valley nor respondent Ms. Nguyen provided a copy of those records as requested. They offered no explanation for that failure to provide the requested records.

XXI.

During the investigation, A.G.'s grandmother, Ms. Smith, volunteered that Spring Valley has made additional mistakes on A.G.'s medications. Spring Valley delivers A.G.'s medications to his home. During a deliver on March 15, 2016, the bottle of Methotrexate leaked in the bag, causing approximately half of the medication to spill onto the outside of the bottle and inside the bag. Spring Valley later provided a replacement bottle.

XXII.

Spring Valley's records do not reflect the additional bottle in the patient profile, although it is noted on the workflow document for Prescription No. #676992. Those records show a fill date and time of April 12, 2016 at 9:59 AM. The status is "deleted." The record shows that Respondent Ms. Nguyen was the "IOU pharmacist", which indicates that she is the pharmacist who provided the remaining medication to complete a previous partial fill.

XXIII.

During the March 15, 2016 inspection, the Board's Inspectors requested a copy of Spring Valley's policies and procedures for compounding nonsterile compounded drug products. Neither Spring Valley nor Ms. Nguyen could provide those written policies and procedures.

XXIV

During the Board's investigation, the Complainant advised the Investigator of a separate filling error by Spring Valley concerning A.G.'s medication. On January 13, 2016, A.G.'s physician send an e-prescription for "Flagyl 250 MG Oral tablet" with notes to compound for "Flagyl Suspension 20 mg per mL, to take 4mL by mouth every 6 hours, for a dosage of 80 mg 4 times a day for 10 days." Spring Valley designated it Prescription No. 675133.

XXV.

On April 25, 2016, Respondent Ms. Nguyen provided a duplicate label for Prescription No. 675133. That duplicate label revealed that Spring Valley dispensed a medication with directions to take "3ML BY MOUTH EVERY 6 HOURS UNTIL GONE." The label also stated "15 Tab METRONIDAZOLE 500MG."

XXVI.

The label shows that Respondent Ms. Nguyen, initials "JTN", verified the medication.

XXVII.

A copy of the prescription the Board Inspector obtained from the pharmacy's archived paper records contained a back label showing the directions "TAKE HALF TABLET BY MOUTH EVERY SIX HOURS UNTIL GONE."

XXVIII.

The pharmacy has none of the compounding records required to show that it compounded the medication correctly. Neither the labels nor the archived paper records for Prescription No. 675133 reveal the medication's concentration.

XXIX.

Ms. Nguyen input the prescription date into Spring Valley's computer system, and she verified the medication was accurate prior to sale. Spring Valley's records are missing all information regarding the person who filled the medication.

XXX.

The Board Inspector found a second instance where Spring Valley failed to adequately label a Flagyl prescription for A.G. in March 2016.

XXXI.

On March 28, 2016, A.G.'s physician transmitted to Spring Valley an e-prescription, Prescription No. #678825, for "Flagyl 250 MG Oral Tablet". The prescription notes called for "Flagyl Suspension 20 mg per ML, to take 4 mL by mouth every 6 hours, for a dose of 80 mg 4 times a day for 10 days."

XXXII.

The duplicate label for that prescription shows directions to take "80 MG (4ML) BY MOUTH EVERY 6 HOURS FOR 10 Days" and "160 MI METRONIDAZOLE 500/ML."

XXXIII.

The duplicate label shows Ms. Nguyen, initials "JTN", verified the medication.

XXXIV.

Spring Valley did not have a copy of the back label in its records.

XXXV.

The workflow records for Prescription No. #678825 show that Ms. Nguyen input the date of the prescription in the pharmacy computer system. They show a fill time of March 28, 2016, at 11:59 AM. They further show that pharmacist Martin Chibueze verified the medication as accurate the same day, at 4:46 PM.

XXXVI.

Respondent Ms. Nguyen could not explain to the Board Investigator the meaning of “160 MI METRONIDAZOLE 500/ML.”

XXXVII.

The label did not indicate the concentration of the medication, so Spring Valley was unable to provide verification that it compounded the medication correctly.

XXXVIII.

On March 15, 2016, Ms. Nguyen provided a statement to the Board’s Reno Office stating that Spring Valley would no longer provide non-sterile compounded products to its patients.

XXXIX.

Pharmacy records indicate the that pharmacy continued to make compounded nonsterile medication, including an additional methotrexate compound on April 12, 2016.

FIRST CAUSE OF ACTION

(Spring Valley Pharmacy)

XL.

NAC 639.945(1)(d) states that “failing strictly to follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling” constitutes “unprofessional conduct and conduct contrary to the public interest.” NRS 639.210(4) lists “unprofessional conduct or conduct contrary to the public interest” as grounds for suspension or revocation of any license or registration issued by the Board. Similarly, NRS 639.255 says the Board may discipline the holder of any license it issued using any of the methods listed therein.

XLI.

Spring Valley violated NAC 639.945(1)(d) when they, without first contacting A.G.’s prescriber for approval to make an adjustment, dispensed Prescription No. 676992 to A.G. with instructions to “GIVE 4ML BY MOUTH EVERY WEEK ON MONDAY (GIVE 25MG/10ML),” instead of “0.4 ML BY MOUTH EVERY WEEK ON MONDAY (25MG/ML)”

as directed by A.G.'s physician. They, and each of them, are subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

SECOND CAUSE OF ACTION

(Spring Valley Pharmacy)

XLII.

NAC 639.930(3) and (4) require a computerized system in a pharmacy to make a record of each modification or manipulation of the information of each prescription in the system. NAC 639.935(g)(3) and (4) likewise requires a pharmacy's computerized system have the capability to print "[t]he history of each prescription filled by the pharmacy, including, without limitation, a record of each [m]odification or manipulation of information concerning the prescription; and . . . [o]ther act related to the processing, filling or dispensing of the prescription."

Moreover, NAC 639.751 requires a pharmacy's computer system to accurately capture the signature, initials or name of the pharmacist or technician who participates in each step of the filling process of a prescription.

Spring Valley Pharmacy's computer system does not accurately capture and retain the information required by NAC 639.751, NAC 639.930(3) and (4), and NAC 639.935(g), as demonstrated by the system's failure to capture, retain, and print the required information for Prescription Nos. 676992, 675133 and 678825. Spring Valley Pharmacy therefore violated each of those regulations and is subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

THIRD CAUSE OF ACTION

(Spring Valley Pharmacy)

XLIII.

NAC 639.751(1)(b) and (2), and NAC 639.930(3) require a pharmacy computer system to have adequate safeguards to identify whether information in the system concerning a prescription has been modified or manipulated, and, where information was modified or manipulated, identify the manner, date and person who modified or manipulated the information. NAC 639.930(4) and

(5) requires the pharmacy's computer system to maintain the information identified per NAC 639.930(3) and to prevent the removal of that information and the record of a prescription once the system assigns a number to the prescription.

XLIV.

By failing to maintain adequate safeguards in its computer system to identify the information required by NAC 639.751(1)(b) and (2) and NAC 639.930(3) as to Prescription Nos. 676992, 675133 and 678825, and by failing to prevent the removal of that information as required by NAC 639.930(4) and (5), Spring Valley violated each of those regulations and is subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

FOURTH CAUSE OF ACTION

(Spring Valley Pharmacy)

XLV.

NRS 454.291(1) requires a pharmacy to maintain accurate records of the purchase and disposition of all its dangerous drugs and to make those records available to inspection by agents and inspectors of the Board. Those records must be maintained for a minimum of two years.

XLVI.

By producing inaccurate records of Prescription No. 676992 to the Board Investigator during the investigation, in particular, by producing a duplicate label for Prescription No. 676992 with the directions "give 0.4mL by mouth every week on Monday (25mg/mL)" and a subsequent copy of the prescription paperwork with different instructions—"give 4mL by mouth every week on Monday (give 25mg/10mL)"—Spring Valley is guilty of violating NAC 639.930(1) and (2) and are subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

FIFTH CAUSE OF ACTION

(Spring Valley Pharmacy)

XLVII.

NRS 639.2801 requires all prescriptions to be dispensed in a container with a label affixed stating, among other things, the date, the manufacturer name or NDC number, the expiration date or BUD, the strength/concentration of the drug, certain warning labels and the directions for use.

XLIII.

NAC 639.6703 requires a pharmacist engaged in compounding nonsterile compounded drug products to label the compounded drug to include the name or the final compounded product or the name of each active ingredient present in the nonsterile compounded drug product, the internal control number assigned to the product and the beyond use date (expiration date) for the product.

XLIX.

By failing to properly label the container for Prescription No. 676992 and Prescription No. 675133 to include an accurate manufacturer name or NDC number, the expiration date or BUD, the strength/concentration of the drug, the proper warning labels and the specific directions for use set by the practitioner, Spring Valley violated NRS 639.2801 and NAC 639.6703 and are subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

SIXTH CAUSE OF ACTION

(Spring Valley Pharmacy)

L.

NAC 639.482(1) requires a pharmacy to maintain all prescription records for a minimum of two years. Subsection 2 of that regulation requires a pharmacy to make all records available for inspection and copying upon request of the Board and its agents, including Board Inspectors and Investigators. By failing to produce and provide to the Board Investigator the billing records

for A.G.'s medications, Spring Valley violated that regulation and is subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

SEVENTH CAUSE OF ACTION

(Spring Valley Pharmacy)

LI.

NRS 454.286(1) requires "[e]very retail pharmacy . . . [that] engages in the practice of dispensing or furnishing drugs to patients shall maintain a complete and accurate record of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise." "The records must be retained for a period of 2 years and must be open to inspection by members, inspectors or investigators of the Board or inspectors of the Food and Drug Administration." NRS 454.286(2).

LII.

By failing to maintain complete and accurate records of all dangerous drugs it purchased and the dangerous drugs it sold, Spring Valley violated NRS 454.286 and is subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

EIGHTH CAUSE OF ACTION

(Spring Valley Pharmacy)

LIII.

NAC 639.247 and NAC 639.67035 require each pharmacy engaged in nonsterile compounding to establish and follow detailed policies and procedures setting the process(es) the pharmacy and its employees must follow and records the pharmacy and its employees must keep to document that process. Those policies and procedures must ensure the quality and safety of compounded drug products and pharmacy personnel.

LIV.

NAC 639.67015 requires a compounding pharmacy to "establish and maintain written policies and procedures for compounding drug products to ensure that each final compounded

drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have.” Those policies and procedures should encapsulate and cause to be put into practice all the requirements of NAC 639.67037.

LV.

By failing to have, and by failing to produce to the Board Investigator, policies and procedures as described above, Spring Valley violated NAC 639.247, NAC 639.67015, NAC 639.67035 and NAC 639.67037.

NINTH CAUSE OF ACTION

(Jessica Nguyen)

LVI.

As the managing pharmacist/pharmacist in charge of Spring Valley at the time of each of the violations alleged herein, Respondent Ms. Nguyen is responsible for those violations, including those of her employees. *See* NRS 639.0087, NRS 639.210(15), NRS 639.220(3)(c), NAC 639.510(2), NAC 639.702; and NAC 639.910(2). Ms. Nguyen’s pharmacist license, Certificate of Registration No. 15397, is therefore subject to discipline, suspension or revocation pursuant to those statutes and regulations, NRS 639.210(4), (9), (11) - (12), (15) and/or (17), as well as NRS 639.230(5) and/or NRS 639.255.

TENTH CAUSE OF ACTION

(Spring Valley Pharmacy and Jessica Nguyen)

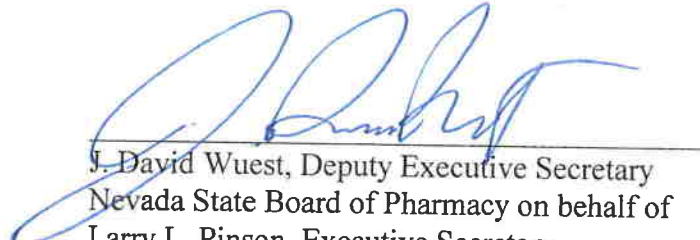
LVII.

As the pharmacy and owner of the pharmacy in which the violations alleged in herein occurred, Respondents Spring Valley and Ms. Nguyen, respectively, are each responsible for the violations set forth above pursuant to NAC 639.702 and NAC 639.945(2). Each of their licenses, Certificate of Registration No. 15397 (Ms. Nguyen), and Certificate of Registration No. PH02375 (Spring Valley) are therefore subject to discipline pursuant to NRS 639.210(4), (9), (11) - (12), (15) and/or (17), as well as NRS 639.230(5) and/or NRS 639.255.

LVIII.

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.

DATED this 14th day of March 2017.



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

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your certificate of registration. To do so, you must mail to the Board within 15 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JESSICA NGUYEN, RPH

Certificate of Registration No. 15397

Respondent.

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

) **CASE NO. 16-022-RPH-S**
)
)
)
)
)

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 Thursday, April 13, 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 14th day of March 2017.



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

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 2017.

JESSICA NGUYEN, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

SPRING VALLEY PHARMACY

Certificate of Registration No. PH02375,

Respondent.

) ANSWER AND
) NOTICE OF DEFENSE

) CASE NO. 16-022-RPH-S

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 2017.

Type or print name

AUTHORIZED REPRESENTATIVE FOR
SPRING VALLEY PHARMACY

MAR - 3 2017

NEVADA STATE BOARD
OF PHARMACY**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

NEVADA STATE BOARD OF PHARMACY,)	CASE NO. 17-004-PT-S
)	
Petitioner,)	
)	
v.)	NOTICE OF INTENDED ACTION
)	AND ACCUSATION
CHELSEA WEISBARTH, PT)	
Certificate of Registration No. PT14657,)	
)	
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.

JURISDICTION**I.**

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because Respondent Chelsea Weisbarth, PT (Ms. Weisbarth), Certificate of Registration No. PT14657, was a registered pharmaceutical technician with the Board at the time of the events alleged herein.

FACTUAL ALLEGATIONS**II.**

In December 2016, CVS Pharmacy #16794 (CVS) notified Board Staff that it terminated Ms. Weisbarth from her employment as a pharmaceutical technician. CVS terminated Ms. Weisbarth's employment for diversion of controlled substances and a dangerous drug. The circumstances leading up to her termination are as follows.

III.

CVS Pharmacy #16794 is located within Target Store T1462 (Target).

IV.

On September 14, 2016, a Target Asset Protection Specialist conducted a live video surveillance in the cosmetics department at Target. He observed Ms. Weisbarth selecting two lipsticks from the shelf and concealing them in her left pocket. She subsequently placed them in her purse and exited the Target store without paying for the lipsticks.

V.

On or about September 20, 2016, the CVS Pharmacy #16794 supervisor contacted the CVS Regional Loss Prevention Manager regarding the theft involving Ms. Weisbarth.

VI.

Approximately a week later, on September 28, 2016, the CVS Regional Loss Prevention Manager interviewed Ms. Weisbarth.

VII.

During the interview and in a written statement, Ms. Weisbarth admitted to the theft of the two lipsticks.

VIII.

Ms. Weisbarth also admitted to diverting one bottle of #30 modafinil 100 mg. tablets and one Viagra 25 mg. tablet. The thefts occurred between January 2016 and September 2016.

IX.

Ms. Weisbarth diverted the drugs by removing the tablet(s) from a stock bottle and placing the tablet(s) in her pocket.

X.

During the interview by the CVS Regional Loss Prevention Manager, Ms. Weisbarth indicated that she diverted the drugs for personal use due to stress in her personal life.

FIRST CAUSE OF ACTION

XI.

Nevada Revised Statutes (NRS) 453.331(d) states, in relevant part, that "[i]t is unlawful

for a person knowingly or intentionally to . . . [a]cquire or obtain . . . possession of a controlled substance . . . by misrepresentation, fraud, forgery, deception, subterfuge or alteration.” NRS 639.210(12) says that a violation or attempt to violate “any law or regulation relating to drugs, the . . . distribution of drugs or the practice of pharmacy . . . committed by the holder of a certificate, license [or] registration” is grounds for suspension or revocation of any certificate, license or permit licensed by the Board.

In diverting controlled substances for personal use as alleged herein, Respondent Ms. Weisbarth, PT, Certificate of Registration No. PT14657, violated NRS 453.331(1)(d), and is subject to discipline pursuant to NRS 639.210(12), as well as NRS 639.255.

SECOND CAUSE OF ACTION

XII.

NRS 453.336(1) states, in relevant part, that “a person shall not knowingly or intentionally possess a controlled substance, unless the substance was obtained directly from, or pursuant to, a [lawful] prescription or order of a [practitioner]”. NRS 639.210(12) says that a violation or attempt to violate “any law or regulation relating to drugs, the . . . distribution of drugs or the practice of pharmacy . . . committed by the holder of a certificate, license [or] registration . . .” is grounds for suspension or revocation of any certificate, license or permit licensed by the Board.

In diverting a dangerous drug and controlled substances for personal use, as alleged herein, Respondent Ms. Weisbarth, PT, Certificate of Registration No. PT14657, violated NRS 453.336(1), and is subject to discipline pursuant to NRS 639.210(12), as well as NRS 639.255.

THIRD CAUSE OF ACTION

XIII.

Nevada Administrative Code (NAC) 639.945(1)(g) states that “[s]upplying or diverting drugs . . . which are legally sold in pharmacies . . . so that unqualified persons can circumvent any law pertaining to the legal sale of such articles” constitutes “unprofessional conduct and

conduct contrary to the public interest.” NRS 639.210(4) says that conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board.

In diverting a dangerous drug and controlled substances for personal use as alleged herein, Respondent Ms. Weisbarth, PT, Certificate of Registration No. PT14657, violated NAC 639.945(1)(g), is guilty of unprofessional conduct and is subject to discipline pursuant to NRS 639.210(4), as well as NRS 639.255.

FOURTH CAUSE OF ACTION


XIV.

NAC 639.945(1)(h) states that “[p]erforming or in any way being a party to any fraudulent or deceitful practice or transaction” constitutes “unprofessional conduct and conduct contrary to the public interest.” NRS 639.210(4) says that conduct that is unprofessional or contrary to the public interest is grounds for suspension or revocation of any certificate, license or permit licensed by the Board.

In diverting a dangerous drug and controlled substances for personal use, as alleged herein, Respondent Ms. Weisbarth, PT, Certificate of Registration No. PT14657, violated NAC 639.945(1)(h), is guilty of unprofessional conduct and is subject to discipline pursuant to NRS 639.210(4), 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 these respondents.

Signed this 2nd day of March, 2017.


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 the Notice of Intended Action and Accusation a written statement showing your compliance.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

y.

CHELSEA WEISBARTH, PT

Certificate of Registration No. PT14657,

Respondent.

CASE NO. 17-004-PT-S

STATEMENT TO THE RESPONDENT

NOTICE OF INTENDED ACTION

AND ACCUSATION

RIGHT TO HEARING

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, April 12, 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 2nd day of March, 2017.


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. 17-004-PT-S
)	
Petitioner,)	
v.)	
)	
CHELSEA WEISBARTH, PT)	ANSWER AND NOTICE
Certificate of Registration No. PT14657,)	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 _____, 2017.

CHELSEA WEISBARTH, PT

DEC - 8 2016

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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

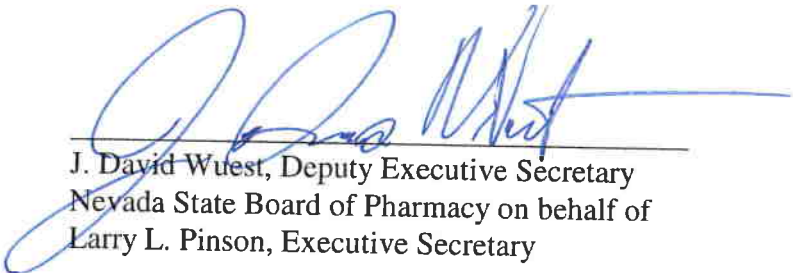
XXXVI.

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,

Petitioner,

v.

MARC ANTHONY BARBOSE, RPH

Certificate of Registration No. 14251

Respondent.

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

) **CASE NO. 16-034-RPH-S**
)
)
)

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.

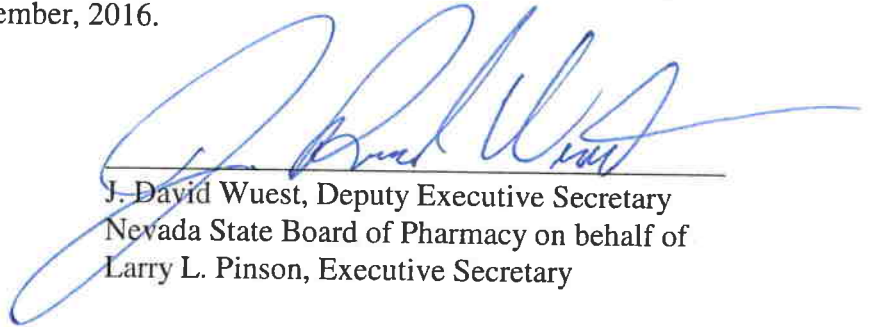
III.

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

JAN - 9 2017

NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

MARC ANTHONY BARBOSE, RPH
Certificate of Registration No. 14251, ANDWELL CARE COMPOUNDING PHARMACY
Certificate of Registration No. PHN02869

Respondents.

Case Nos. 16-034-RPH-S
16-034-PH-S**RESPONDENT MARC ANTHONY
BARBOSE, RPH'S ANSWER AND
NOTICE OF DEFENSE**

Marc Anthony Barbose, RPH ("Mr. Barbose"), by and through his counsel of record McDonald Carano Wilson LLP, in answer to the Notice of Intended Action and Accusation ("Accusation") filed in the above-entitled matter before the Nevada State Board of Pharmacy (the "Board"), 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:

Marc Barbose held a membership interest in Respondent Well Care Discount Pharmacy LLC dba Well Care Compounding Pharmacy LLC ("Well Care") until April 24, 2016.¹ At the time of the inspection identified in the Accusation, Mr. Barbose was no longer a member of Well Care and, on the same date, provided the Board written notification that he was no longer Well Care's pharmacist in charge ("PIC").²

For the Board's further consideration, Mr. Barbose states that he performed his professional duties in accordance with and under the belief that Well Care was properly categorized as a Section 503A compounding pharmacy under the Federal Food, Drug, and

¹ Mr. Barbose is currently employed at a compounding pharmacy, but the pharmacy does not engage in sterile product compounding.

² On May 3, 2016, Mr. Barbose sent a subsequent letter to the Board notifying it that he would be in attendance during the May 2-4, 2016 Well Care inspection, but he was not reinstated as the PIC.

Cosmetic Act (the "Act"). Thus, all products were made pursuant to a physician's prescription for a specific patient and, in operating its business, Well Care followed United States Pharmacopeia – National Formulary (USP-NF) 795/797 compounding standards and guidelines.³ When Mr. Barbose informed the inspectors from the Board and U.S. Food and Drug Administration ("FDA") that he believed Well Care was a Section 503A compounding pharmacy, he was informed that Well Care would be inspected and reviewed as a bulk producing compounding or manufacturing facility under Section 503B of the Act. Section 503B compounding facilities follow different standards, Compounding/Pharmaceutical Quality/Manufacturing Standards, Current Good Manufacturing Practice ("cGMP").

In November 2015, Mr. Barbose was aware of the changing and more stringent regulations in the compounding pharmacy industry so Well Care undertook efforts to obtain accreditation by the Pharmacy Compounding Accreditation Board ("PCAB").⁴ PCAB is a service of the Accreditation Commission for Health Care ("ACHC"), an independent, private, not-for-profit corporation. The thorough accreditation process took more than six months and resulted in Well Care modifying and updating its processes and procedures to achieve accreditation. The process encompassed both non-sterile (creams, capsules, solutions) and sterile (injections, eye drops, nasal sprays) compounding standard operating procedures ("SOPs") and techniques. Well Care undertook the accreditation process because Mr. Barbose believed that it would be beneficial to patients because it would enhance Well Care's pharmacy operations through process improvement. Well Care learned it achieved accreditation on May 24, 2016, just weeks after the Board's and U.S. Food and Drug Administration's ("FDA") May

³ Nevada Administrative Code ("NAC") 639.670(1)(c) adopts the United States Pharmacopeia - National Formulary, 2008 edition, in full.

⁴ To that end, Mr. Barbose shares, and is supportive of, the Board's mission to protect the public from injury or illness. Mr. Barbose has been a licensee for 18 years and has not had any disciplinary action taken against him because of his commitment to his profession. As a result, Mr. Barbose desires to work with the Board to achieve the joint goal of protecting public health and safety.

2, 2016 inspection. See <http://www.pcab.org/accredited-locations.html> (search location: Nevada).

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

I.

Mr. Barbose admits that the Board has jurisdiction over this matter and him.

II.

Mr. Barbose denies that he was the Pharmacist in Charge at respondent Well Care at the time of the events alleged in the Accusation. By way of further response, Mr. Barbose states that he held a membership interest in Well Care until on or about April 22, 2016. Mr. Barbose resigned as the pharmacist in charge on April 22, 2016 and notified the Board of the change in status via facsimile as required by NAC 639.540. When Well Care learned of the Board's and FDA's impending May 2, 2016 inspection, Mr. Barbose agreed to provide Well Care assistance during the inspection and until Well Care had staffed a suitable replacement pharmacist in charge. On May 3, 2016, Mr. Barbose notified the Board that he would be present during the Well Care inspection. Mr. Barbose denies the remaining allegations contained in said paragraph.

III.

Mr. Barbose is without sufficient knowledge or information about the investigation performed by the Board or the FDA to form a belief as to the truth or falsity of the allegations contained in paragraph III and therefore denies the same. Upon information and belief, Mr. Barbose admits that a patient complained about suffering from an infection after obtaining a sterile product compounded and dispensed by Well Care. By way of further response, upon information and belief, the compounded and dispensed product was Estradiol Valerate Injection ("EVI"). The patient reportedly suffered an infection and was treated in an emergency room. The patient only obtained EVI one time from Well Care although, upon information and belief,

the patient was receiving a high dose of hormones through other prescriptions not filled by Well Care. The patient refused Well Care's offer to sell the patient sterile syringes for use with EVI. During the May 2, 2016 inspection, Mr. Barbose presented copies of the itemized receipt to the Board's and FDA's respective inspectors.

IV.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph IV regarding the activities of the FDA inspectors and therefore denies the same.

V.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph V regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose denies that while he was a member of Well Care that it did not have or failed to follow written policies and procedures as alleged therein. Mr. Barbose denies the remaining allegations in paragraph V(1).

VI.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph VI regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph VI(2).

VII.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph VII regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further

response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph VII(3).

VIII.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph VIII regarding the activities and observations of the FDA's and Board's respective inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph VIII(4).

IX.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph IX regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph IX(5).

X.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph X regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph X(6).

XI.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XI regarding the activities and observations of the FDA's and Board's respective inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph XI(7)-(9).

XII.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XII regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph XII(10)-(11).

XIII.

Mr. Barbose denies that during the time that he was a member of Well Care that there was not a program in place to review any discrepancy and failure of any batch of its sterile products. By way of further response, Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XIII regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph XIII(12).

XIV.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XIV regarding the activities and

observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph XIV(13).

XV.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XV regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph XV(14).

XVI.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XVI regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph XVI(15)-(17).

XVII.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XVII regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements. Mr. Barbose denies the remaining allegations in paragraph XVII.

XVIII.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XVIII regarding the activities and observations of the FDA's inspectors and therefore denies the same.

XIX.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XIX regarding the activities and observations of the FDA's inspectors and therefore denies the same.

XX.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XX regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, Mr. Barbose states that, while he was a member of Well Care, it had systems in place to ensure full compliance with the pertinent laws, regulations and licensing requirements.

XXI.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XXI regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, the allegations do not concern acts or omissions of Mr. Barbose and therefore denies the same.

XXII.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XXII regarding the activities and observations of the FDA's inspectors and therefore denies the same. By way of further response, the allegations do not concern acts or omissions of Mr. Barbose and therefore denies the same.

XXIII.

Mr. Barbose is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph XXIII and therefore denies the same.

XXIV.

FIRST CAUSE OF ACTION
Deficient Physical Environment
(All Respondents)

Mr. Barbose states that the allegations contained in paragraph XXIV contain legal conclusions and therefore denies the same.

XXV.

SECOND CAUSE OF ACTION
Inadequate Protective Apparel
(All Respondents)

Mr. Barbose states that the allegations contained in paragraph XXV contain legal conclusions and therefore denies the same.

XXVI.

THIRD CAUSE OF ACTION
Deficient Cleaning Process
(All Respondents)

Mr. Barbose states that the allegations contained in paragraph XXVI contain legal conclusions and therefore denies the same.

XXVII.

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

Mr. Barbose states that the allegations contained in paragraph XXVII contain legal conclusions and therefore denies the same.

XXVIII.

FIFTH CAUSE OF ACTION

Deficient Testing and Monitoring of Physical Environment
(All Respondents)

Mr. Barbose states that the allegations contained in paragraph XXVIII contain legal conclusions and therefore denies the same.

XXIX.

SIXTH CAUSE OF ACTION

Deficient Product Monitoring
(All Respondents)

Mr. Barbose states that the allegations contained in paragraph XXIX contain legal conclusions and therefore denies the same.

XXX.

SEVENTH CAUSE OF ACTION

Deficient Staff Training
(All Respondents)

Mr. Barbose states that the allegations contained in paragraph XXX contain legal conclusions and therefore denies the same.

XXXI.

EIGHTH CAUSE OF ACTION

Failure to Keep Accurate Records
(All Respondents)

Mr. Barbose states that the allegations contained in paragraph XXXI contain legal conclusions and therefore denies the same.

XXXII.

NINTH CAUSE OF ACTION

Beyond Use Dating
(All Respondents)

Mr. Barbose states that the allegations contained in paragraph XXXII contain legal conclusions and therefore denies the same.

XXXIII.

TENTH CAUSE OF ACTION

Inadequate Labeling
(All Respondents)

Mr. Barbose states that the allegations contained in paragraph XXXIII contain legal conclusions and therefore denies the same.

XXXIV.

ELEVENTH CAUSE OF ACTION

Pharmacy Technician Ratio
(Respondent Well Care and Barbose)

Mr. Barbose states that the allegations contained in paragraph XXXIV contain legal conclusions and therefore denies the same.

XXXV.

TWELVTH CAUSE OF ACTION

Managing Pharmacist Responsibility
(Respondent Marc Barbose)

Mr. Barbose states that the allegations contained in paragraph XXXV contain legal conclusions and therefore denies the same.

XXXVI.

THIRTEENTH CAUSE OF ACTION

Pharmacy Responsibility
(Well Care Compounding Pharmacy)

Mr. Barbose states that the allegations contained in paragraph XXXVI do not concern acts or omissions of Mr. Barbose and therefore denies the same.

Dated this 4th day of January, 2017.

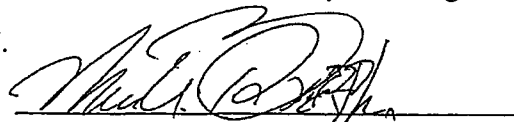
McDonald Carano Wilson LLP

By: Kristen T. Gallagher
Kristen T. Gallagher, Esq.
Lucas Foletta, Esq.
2300 W. Sahara Avenue, Suite 1200
Las Vegas, NV 89107
Attorneys for Respondent Marc A. Barbose

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 4th day of January, 2017.

By:

A handwritten signature in dark ink, appearing to read 'Marc A. Barbose', written over a horizontal line.

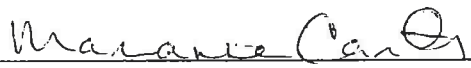
Marc A. Barbose, RPH

CERTIFICATE OF SERVICE

I hereby certify, under penalty of perjury, that I am an employee of McDonald Carano Wilson LLP and that on this 4th day of January, 2017 I caused to be delivered a true copy of the **RESPONDENT MARC ANTHONY BARBOSE'S ANSWER AND NOTICE OF DEFENSE** as follows:

Via U.S. Mail, postage prepaid
Larry L. Pinson, Executive Secretary
Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

Via U.S. Mail, postage prepaid & Email
S. Paul Edwards
General Counsel
Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509
pedwards@pharmacy.nv.gov


Marianne Carter

376294