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/*10*ML)." (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/*10*ml) Milligram, Oral *4*ml once a week on Monday." (Emphasis added.) The notes to the pharmacist similarly stated: "Compound to Methotrexate 25mg/*10*ml 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/*10*ml) Milligram, Oral *4*ml 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/*10*ML)," 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 warring 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 proceedures as decribed 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.

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY Petitioner, vs. JESSICA NGUYEN, RPH, Certificate of Registration No. 15937; and SPRING VALLEY PHARMACY, Certificate of Registration No. PH02375, Respondents.	Case Nos.: 16-022-RPH-S; and 16-022-PH-S. **ANSWER, NOTICE OF DEFENSE, AND REQUEST FOR HEARING**

COMES NOW Spring Valley Pharmacy and Jessica Nguyen ("Respondents") by and through their counsel Jude Edward Nazareth, Esq., of Montez Nazareth Law to answer to the Nevada State Board of Pharmacy's Notice of Intended Action and Accusation ("Notice") as follows:

As to Paragraphs I - III of the Notice, Respondents admit the allegations contained therein.

As to Paragraph IV of the Notice, Respondents admit the Board Inspector "requested to see the prescription and records related to the drug." Except as heretofore admitted, Respondents are without sufficient knowledge or information to form a belief

as to the truth or falsity of the matters alleged and/or deny the allegations therein.

As to Paragraph V of the Notice, Respondents admit the allegations contained therein.

As to Paragraph VI of the Notice, Respondents are without sufficient knowledge or information to form a belief as to the truth or falsity of the matters alleged and/or deny the allegations therein.

As to Paragraphs VII – IX of the Notice, Respondents admit the allegations contained therein.

As to Paragraphs X – XIII of the Notice, Respondents are without sufficient knowledge or information to form a belief as to the truth or falsity of the matters alleged and/or deny the allegations therein.

As to Paragraph XIV of the Notice, Respondents admit the allegations contained in the first sentence therein. Except as heretofore admitted, Respondents are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining matters alleged and/or deny the allegations therein.

As to Paragraph XV of the Notice, Respondents admit the allegations contained therein.

As to Paragraphs XVI – XVII of the Notice, Respondents are without sufficient knowledge or information to form a belief as to the truth or falsity of the matters alleged and/or deny the allegations therein.

As to Paragraph XVIII of the Notice, Respondents admit the allegations contained in the first sentence therein. Except as heretofore admitted, Respondents are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining matters alleged and/or deny the allegations therein.

As to Paragraphs XIX - XXIV of the Notice, Respondents are without sufficient knowledge or information to form a belief as to the truth or falsity of the matters alleged and/or deny the allegations therein.