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MATRIX GUIDELINE FOR DISCIPLINARY ACTIONS

	1st Action	2nd Action	3rd Action
Non ingested error	Letter	Letter	Hearing
No counseling	$750.00	Counseling CE + $1000.00	Hearing
Attorney Fees and Costs	Actual	Actual	Actual
Ingested no potential harm	$500.00	$1000.00	Hearing
Ingested with potential harm or adverse outcomes	$1000.00	Hearing	Hearing
Ingested with negative outcome or patient discomfort. No institution intervention	Hearing	Hearing	Hearing
Ingested with significant negative health circumstance. With institution admit	Hearing	Hearing	Hearing
Ingested with death related to inappropriate drug therapy	Hearing	Hearing	Hearing

The investigative committee will review each case individually and may recommend a board hearing, particularly with mitigating circumstances such as inappropriate technician involvement or pharmacist malfeasance.

In certain cases with ingested errors and significant negative health circumstances requiring institutional care, the investigative committee recommendation will be a board hearing.

In all death cases resulting from inappropriate drug therapy a board hearing will occur.

Attorney fees and costs may be added in contested disciplinary actions requiring extensive attorney preparation and presentation and are not described in the above matrix.

The board has directed that ownership may be charged in disciplinary cases. In non-ingested errors copies of admonition letters will be sent to management. Accumulative actions for ownership monitoring will be based upon a 3 year period. All actions including non-ingested errors will be given a case number and monitored.

The Board has the authority to fine from $0.00 to $10,000 for each Cause of Action.

Updated May 2019

FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
RPH DC and WB did not complete required CEs.	N/A	DC: $500 fine; $1,000 administrative fee; additional CEs; attend 3 of the next 4 Board meetings; complete and pass Nevada law. WB: $500 fine; $1,000 administrative fee; additional CEs; attend 3 of the next 4 Board meetings.	
RPH SB failed to speak to the prescriber before, at the time or after she declined to fill a patient's prescription for clopidogrel.	N/A	Fined $500; administrative fee of $1,000; 4 hours of CE related to cardiology or cardiac drugs.	Fined $1,000; an administrative fee of $2,000; establish Board-approved policies and procedures that are consistent with Nevada law and retrain its current and future pharmacists regarding the same.
RP allowed unlicensed staff to prescribe/order dangerous drugs and use his authority to obtain, administer, access and/or possess an inventory of dangerous drugs when he was not onsite and without his direct supervision. RP did not have a bona fide therapeutic relationship with the patients. RP purchased compounded dangerous drugs from a pharmacy not licensed with the Board.	N/A	RP shall receive a public letter of reprimand; his CS registration shall be placed on probation for a period of 12 months; fined $5,000; administrative fee of $2,500; establish policies and procedures. RP's offices/clinics are subject to quarterly inspections for one year.	N/A
RPH NR verified a prescription for 30 chlordiazepoxide 25 mg. capsules which was labeled and dispensed to the wrong patient. RPH JA failed to counsel the patient. PT LP deleted the prescription from the pharmacy system. ML was the managing pharmacist.	N/A	NR shall receive a letter of reprimand; fined $2,750; 2 additional hours of CE on error prevention. JA shall receive a letter of reprimand; fined $750; 2 additional hours of CE on patient counseling. LP fined $500; $1,000 administrative fee; attend three of the Board's next four	$1,000 fine; $1,500 administrative fee.

FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
		meetings on disciplinary day. ML shall complete 4 additional hours of CE on pharmacy management.	
PT MC diverted controlled substances from her employing pharmacy.	N/A	Revocation of pharmaceutical technician registration.	N/A
RPH SB did not renew his registration and worked 244 days unlicensed. He was also the PIC.	N/A	Fined $2,500 and $1,000 administrative fee.	Fined $5,000 fine and $2,683.99 administrative fee
RPH CD verified Risperidone 2 mg. tablets in the prescription bottle as the correct product for dispensing when the physician prescribed Ropinirole 2 mg. tablets. CD failed to adequately provide counseling.	N/A	Letter of reprimand; fined $1,000; $1,000 administrative fee; complete 2 CEs on error prevention.	WG-NV fined $1,000; $1,000 administrative fee. WG-FL fined $2,000; $1,000 administrative fee.
RPH JS dispensed medication labeled with incorrect instructions.	N/A	Letter of reprimand; $1,000.00 fine; $1,000.00 administrative fee; complete two additional CEs on error prevention.	Fined $1,000.00; $1,000.00 administrative fee.
RPH JCH filled and dispensed a Vancomycin prescription without the necessary knowledge and proper training, accepting verbal prescriptions from non-practitioners and failing to follow the prescription written by the prescriber.	N/A	Registration revoked; the revocation is stayed with conditions: take and pass the NAPLEX and MPJE; pay a $5,000.00 fine; pay a $1,250.00 administrative fee. Registration shall be placed on probation for four years during which time he cannot work as a managing pharmacist in any Nevada-licensed pharmacy; cannot engage in any form of compounding; and he must attend two Board meetings each year	$5,000.00 fine; $1,250.00 administrative fee; subject to quarterly inspections for one year at its own expense.

FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
		during the four year probationary periods.	
RPH WM was the managing pharmacist accountable for violations by personnel in his employ regarding the filling, compounding and record keeping of drug products	N/A	Letter of reprimand; $500.00 fine; $500.00 administrative fee.	$1,500.00 fine; $2,500.00 administrative fee; purchase software for tracking components used in its compounding services and the products it compounds; create new policies and procedures regarding medication management and compounding; subject to quarterly inspections at their own expense.
RPH KB verified data as correct when it was not and dispensed Prednisone 50 mg. tablets when 5 mg. tablets was prescribed.	The patient experienced a temporary negative outcome as a result of the error	$1,000.00 fine; an administrative fee of $500.00; complete two additional CEs related to prescription verification/error prevention and 2 CEs on to DUR warnings.	Pay an administrative fee of $1,000.00.
PT GO dispensed a prescription drug to the wrong patient.	N/A	N/A	$500 fine; $750 administrative fee.
RPH SD made false adjustments to the Tramadol inventory. He voluntarily surrendered his registration as discipline. RPH MK was the managing pharmacist and did not report the Tramadol losses to the DEA or Board.	N/A	SD imposed $600 administrative fee. May not reapply for 1 year. MK to receive letter of reprimand; $250 fine; 2 additional CEs.	$1,000 administrative fee; implement new policies and procedures.
APRN MC allowed non-practitioner/non-licensed staff to possess or prescribe dangerous drugs and/or to obtain, access, possess and store dangerous drugs and/or administer drugs when she was not on site at the facility, before she examined the patient and before she wrote a patient-specific order.	N/A	Public letter of reprimand; pay a $3,000.00 fine and $1,000.00 in attorney's fees and costs. MC shall not engage in any practice in which a substantial portion of the practice is providing injections and/or intravenous infusions of vitamins or fluids for rehydration.	N/A

FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
RPH TS verified as accurate, when it was not, the data and final product of a prescription resulting in the pharmacy dispensing amlodipine besylate 10mg. tablets rather than the amitriptyline 10mg. tablets as prescribed and failed to adequately provide patient counseling.	None	Public letter of reprimand; pay a $750.00 fine, and complete 4 additional hours of CE on error prevention and patient counseling	Pay a $500.00 fine and $750.00 in fees and costs.
PT JJ admitted to diverting of 32 Hydrocodone 10/325 mg. tablets for self-use from his employing pharmacy.	N/A	Revocation of pharmaceutical technician registration.	N/A
PT KT admitted to diverting approximately 1,000 Tylenol with Codeine #4 tablets from her employing pharmacy for self-use.	N/A	Revocation of pharmaceutical technician registration.	N/A
RE failed to timely renew his CS Registration, which expired on October 31, 2018. He wrote 189 prescriptions for controlled substances between November 1, 2018 and March 28, 2019, without a valid registration.	N/A	Pay a fine of $1,500.00 and $1,404.52 in attorney's fees and costs.	N/A
SL executed a plea agreement with the United States Attorney's Office for the district of Nevada relating to unprofessional and illegal conduct in prescribing dosages and amounts of Oxycodone and Hydrocodone to patients outside the usual course of his professional practice and without a legitimate medical purpose.	N/A	In lieu of appearing at a hearing, the SL voluntarily surrendered his Nevada CS registration and agreed to pay $500.00 in attorney's fees and costs.	N/A
RPH SL served with an Accusation related to unprofessional and illegal conduct in filling approximately 380 fraudulent prescriptions for Oxycodone-Acetaminophen and	N/A	In lieu of appearing at a hearing, SL voluntarily surrendered his Nevada CS registration and agreed to pay $750.00 in attorney's fees and costs.	N/A

FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
Hydrocodone-Acetaminophen.			
TG served with an Accusation related to unprofessional and illegal conduct in creating fraudulent prescriptions for Oxycodone-Acetaminophen and Hydrocodone-Acetaminophen.	N/A	In lieu of appearing at a hearing, TG voluntarily surrendered his Nevada CS registration.	N/A

5A

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NOS. 19-090-CS-S**
	)	
Petitioner,	)	**NOTICE OF INTENDED ACTION**
v.	)	**AND ACCUSATION**
	)	
CHRISTOPHER NEVAREZ, M.D.,	)	
Certificate of Registration No. CS19561,	)	
	)	
Respondent.	/	

J. David Wuest, 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 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Christopher Nevarez, M.D., Certificate of Registration No. CS19561 ("Dr. Nevarez") held a Board-issued controlled substance registration.

FACTUAL ALLEGATIONS

II.

In February 2018, Respondent Dr. Nevarez was the medical director of Push IV, LLC. ("Push IV"). Non-respondent Noah Auspitz owned Push IV.

III.

At that time, Push IV provided on-site and off-site medical treatment to patients, including the administration of dangerous drugs through intravenous ("IV") therapy and/or

injections using registered nurses ("RNs") and licensed paramedics (collectively "Non-practitioner Staff Members").

IV.

Dr. Nevarez allowed Push IV's Non-practitioner Staff Members to possess the information and keys necessary to access and possess drugs from Push IV's inventory of dangerous drugs without a licensed practitioner present.

V.

Under Dr. Nevarez's direction, Push IV's Non-practitioner Staff Members accessed and possessed Push IV's inventory of dangerous drugs and provided supplies of dangerous drugs to RNs and paramedics without a practitioner on site, without a practitioner's direct supervision, before Dr. Nevarez or any other practitioner examined the patient, and before there was a patient-specific and medication-specific written order for the patient and/or the medication.

VI.

Dr. Nevarez directed the Non-practitioner Staff Members who were employed by Push IV to possess and control dangerous drugs from Push IV's inventory, including storing dangerous drugs in their cars or at their homes, without a practitioner on site, without direct practitioner supervision, without a patient-specific and medication-specific written order for the patient and/or medication.

VII.

Dr. Nevarez allowed Non-practitioner Staff Members to transport the dangerous drugs he put into their possession or that he allowed them to possess and control without a patient-specific and medication-specific order.

VIII.

Dr. Nevarez frequently had no contact—did not examine and did not establish a *bona fide* therapeutic relationship with the patient—until after one of Push IV's Non-practitioner Staff Members transported the dangerous drugs in his/her possession to the patient's location.

IX.

For off-site medical treatment, once a Non-practitioner Staff Member arrived at the patient's location, the Non-practitioner Staff Member would examine the patient and discuss why an IV or injection would be beneficial to the patient.

X.

The Non-practitioner Staff Member would then communicate his/her assessment of the patient to Dr. Nevarez by telephone or text, to which Dr. Nevarez would then approve the medication by text.

XI.

Through that exam process, Dr. Nevarez often did not speak or communicate directly with the patient.

XII.

Push IV and its Non-practitioner Staff Members often provided medical treatment to patients at Push IV's physical location in a similar fashion when Dr. Nevarez was not on site.

XIII.

Under Dr. Nevarez's direction, Push IV purchased dangerous drugs and prescription-only supplies from State Surgical Supply, in Siloam Springs, Arkansas.

XIV.

State Surgical Supply sold dangerous drugs and prescription-only supplies to practitioners in Nevada, included Dr. Nevarez and Push IV.

XV.

State Surgical Supply is not licensed in Nevada.

APPLICABLE LAW

XVI.

No person may possess a dangerous drug in Nevada without specific statutory authority to do so. *See* NRS 454.213, NRS 454.316, NRS 454.321.

XVII.

A practitioner can give a registered nurse limited authority to possess and administer dangerous drugs without the practitioner onsite by way of NRS 454.213(1)(c), which says in relevant part:

> a drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, *or pursuant to a chart order, for administration to a patient at another location.*

NRS 454.213(1)(a)(*emphasis added*); *see also* NRS 639.100.

XVIII.

Chart orders must be written (NRS 454.223) and are patient-specific and medication-specific.[1]

XIX.

"Except as otherwise specifically provided, every person who violates any provision of NRS 454.181 to 454.371, inclusive, is guilty of a misdemeanor." NRS 454.356.

XX.

A practitioner must first establish a *bona fide therapeutic relationship* with a patient by examination before he or she can determine that a medication is medically necessary and direct and/or authorize an RN to possess and administer a dangerous drug on-site or issue a chart order for off-site administration of a dangerous drug to treat the patient's medical condition. *See* NAC 639.945(1)(o) and NRS 454.213(1)(a).

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[1] *See* NRS 639.004 "Chart order" means an order entered on the chart of a patient in a hospital, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

XXI.

> [A] bona fide therapeutic relationship between the patient and practitioner shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics . . . by the practitioner within the 6 months immediately preceding the date the practitioner . . . prescribes a drug to the patient and, as a result of the examination, the practitioner diagnosed a condition for which a given drug therapy is prescribed.

NRS 639.945(3).

XXII.

> An outsourcing facility that is engaged in the compounding of sterile drugs in this State [Nevada] or for shipment into this State shall:
>
> 1. Obtain a license from the Board as a manufacturer in accordance with NRS 639.100 and 639.233;
> 2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and
> 3. Comply with all the requirements of 21 U.S.C. § 353b.

NAC 639.6915

XXIII.

"Supplying . . . medicines, substances or devices which are legally sold in pharmacies or by wholesalers, 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." NAC 639.945(1)(g).

XXIV.

A licensee "[p]erforming any of his or her duties as the holder of a license, certificate or registration issued by the Board . . . in an incompetent, unskillful or negligent manner" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(i).

XXV.

"Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(k).

XXVI.

The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

XXVII.

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).

XXVIII.

Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(12).

FIRST CAUSE OF ACTION

Unlawful Access and Possession of Dangerous Drugs - Statutory Violations

XXIX.

By allowing Push IV's Non-practitioner Staff Members to operate Push IV and to use Dr. Nevarez's authority as a practitioner to obtain, access, possess and/or store dangerous drugs when he was not on site, without a proper examination, without direct supervision and before he wrote a patient-specific order, Dr. Nevarez violated, or assisted and abetted Push IV's staff in violating, NRS 454.213(1), NRS 454.316 and/or NRS 454.356.

SECOND CAUSE OF ACTION
Unlawful Access and Possession of Dangerous Drugs – Unprofessional Conduct

XXX.

By allowing Push IV's Non-practitioner Staff Members to operate Push IV and to use Dr. Nevarez's authority as a practitioner to obtain, access, possess and/or store dangerous drugs when he was not on site, without a proper examination, without direct supervision and before he wrote a patient-specific order, Dr. Nevarez engaged, or assisted and abetted Push IV's staff to engage, in unprofessional conduct as defined in NAC 639.945(1)(g), (i), and (k).

THIRD CAUSE OF ACTION
Unlawful Administration of Dangerous Drugs – No Bona Fide Therapeutic Relationship and No Authority to Determine Medical Necessity

XXXI.

By authorizing Push IV's Non-practitioner Staff Members to use his authority to operate Push IV, to administer a dangerous drug to patients who had not been examined by a practitioner, where he did not have a *bona fide* therapeutic relationship and for whom he had not diagnosed or determined that a dangerous drug was medically necessary, Dr. Nevarez violated, and/or aided and abetted Push IV's staff in violating Nevada law, including NRS 454.221(1). He also acted unprofessionally. *See* NAC 639.945(1)(k) and (o).

FOURTH CAUSE OF ACTION
Purchasing Dangerous Drugs and Prescription Only Supplies from an Unlicensed Pharmacy

XXXII.

By purchasing sterile compounded dangerous drugs from a pharmacy not licensed with the Board, Dr. Nevarez violated, or assisted and abetted that pharmacy in violating, NRS 639.233, NRS 639.285 and/or NAC 639.6915. Because of that conduct, Dr. Nevarez's controlled substance registration, Certificate of Registration No. CS19561 is subject to discipline pursuant to NRS 639.210(4) and (12), NRS 453.236(1)(d); NRS 453.241(1) and/or NRS 639.255.

XXXIII.

For the violations and conduct alleged in paragraphs II through XXXII above, Dr. Nevarez's Controlled Substance Registration, Certificate of Registration No. CS19561 is subject to discipline pursuant to NRS 453.236(1)(d), NRS 453.241(1), NRS 639.210(4) and (12) and/or NRS 639.255.

XXXIV.

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

Signed this 12th day of June 2019.

J. David Wuest, R.Ph., 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. NRS 233B.127(3). 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. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-090-CS-S**
	)	
Petitioner,	)	
v.	)	
	)	**STATEMENT TO THE**
CHRISTOPHER NEVAREZ, M.D.,	)	**RESPONDENT**
Certificate of Registration No. CS19561,	)	**NOTICE OF INTENDED ACTION**
	)	**AND ACCUSATION**
Respondent.	/	**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 and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, 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 show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). 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. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 17, 2019, 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.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of June, 2019.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 13th day of June, 2019, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

CHRISTOPHER NEVAREZ, MD
4315 DEAN MARTIN DR #230
LAS VEGAS, NV 89148

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. CHRISTOPHER NEVAREZ, M.D., Certificate of Registration No. CS19561, Respondent.	)	CASE NO. 19-090-CS-S ANSWER AND NOTICE OF DEFENSE

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").

None.

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

Please see attached statement.

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 30 day of June, 2019.

CHRISTOPHER NEVAREZ, M.D.

With regard to the allegations in the Notice of Intended Action and Accusation, I previously responded on March 9, 2018 to a letter of investigation from the Nevada Board of Pharmacy ("BOP") dated February 27, 2018. That investigation was prompted by complaints related to Push IV, were I have served as medical director since 2015. Push IV is an infusion clinic which caters to Las Vegas visitors and residents seeking hangover relief and/or vitamin supplementation. As the Board is no doubt aware, such infusion clinics have become very popular in Las Vegas and across the country in recent years. It is my understanding that the Board inspected several Las Vegas IV infusion clinics in 2018, prompted by complaints by competing clinics.

As a preliminary matter, I wish to make clear that Push IV has not used emergency medical technicians or paramedics (collectively, "EMTs") to provide infusion services since early 2018. Despite my due diligence efforts in setting up Push IV, discussed below, we were not informed and not aware until the Board's investigation that EMTs are not considered qualified to provide anything other than medical assistant services outside of an emergency response environment.

Additionally, the Board should be aware that I recently resigned as Medical Director of Push IV, effective July 15, 2019.

Due Diligence

I became Medical Director of Push IV in 2015. In setting up operations with Push IV owner Noah Auspitz, I conducted my own due diligence rather than relying on what other area infusion clinics considered "compliant" or "acceptable". This due diligence included direct and transparent communication with both the Nevada State Board of Medical Examiners (NBME) and the Nevada State Board of Pharmacy ("BOP").

On September 1, 2015, I emailed J. David Wuest R. Ph., then Deputy Secretary of the BOP. (See Exhibit 1). I wrote to ask if adding Zofran and/or Toradol to Push IV's services would be permitted. I explained to Mr. Wuest at that time that Push IV "is currently utilizing licensed nurses and medics to start IV's and administer prefabricated solutions of normal saline as a treatment for hangovers." Mr. Wuest replied on September 3, 2015, asking that I call him to discuss. If nothing else, this

signifies the BOP was aware of Push IV's operations since 2015, but we were not informed until under investigation in 2018 that providing services through EMTs was not permitted.

On December 8, 2015, I emailed Todd Rich, then Deputy Executive Director of the NBME. (See Exhibit 2). I wrote to request clarification of Nevada's corporate practice of medicine prohibitions as related specifically to medical spas. I wrote to Mr. Rich,

> "I'm currently medical director for an up and coming medical spa in Las Vegas. At present, we provide intravenous fluids for purposes of health maintenance, vitamin replenishments, and of course hangover recovery. I'm attempting to ensure that all boxes are checked and t's are crossed as we move forward. I joined the americanmedspa.org in hopes of fully outlying [sic] and understanding those that can and should be involved in med spas.... [A]s I understand [corporate practice of medicine] non licensed personnel cannot own med spas in that they cannot dictate medical policy to medical personnel. I have some current business partners who started this particular med spa concept who are not licensed medical providers and I'm working to make sure our business model isn't in violation of current Nevada law." (Emphases added).

Mr. Rich replied, in part, "The subject of med spas is not really contemplated in the Medical Board's governing statutes" and "The medical spa issue in Nevada is one that could use some clarity relative to the Nevada Revised Statutes (NRS). It has not been well defined by the Nevada Legislature, and is not defined in the Board of Medical Examiner's (Board) governing statutes, chapter 630." (Emphasis added). It appears I was trying to understand and ensure compliance for a business model that was "not really contemplated" and inherently unclear under Nevada law.

In addition, in 2016 Mr. Auspitz sought a legal guidance regarding the potential roles and limitations of various levels of practitioners and personnel within Push IV's business model. Although counsel recommended practitioner assessment rather than standing orders, and advised against using EMTs to provide infusion services, I was never provided a copy of that legal

memo. Instead, Mr. Auspitz told me only that he had consulted an attorney regarding compliance. I suppose I had assumed that Mr. Auspitz was adhering to legal advice in pursuing operations as Push Initially did, it never occurred to me that he would not follow his counsel's guidance.

EMT Services

I have been an emergency department physician in Las Vegas for 8 years. I am accustomed to working closely with EMTs, and I am very familiar with their training and skills. My communication with and orders for EMTs are often carried out by telephone. But for legal limitations, I would feel quite confident in delegating many invasive tasks to EMTs. Compared to emergency response in the field, IV hydration on a typically healthy individual in a calm, controlled setting would easily fall within an EMT's skill set.

I can tell the Board that I sincerely believed I had "done my homework" to ensure both legal compliance and patient safety at Push IV. Both the BOP and the NBME were informed of Push IV's operations from the outset as I sought guidance for a business model not really addressed under Nevada law. Although I was requesting assistance and clarification, there was little provided, or possibly even available to the Boards at that time. Furthermore, I had no reason to doubt the clinical skills and familiar communication methods of EMTs, which I witnessed first hand nearly every day in the emergency department.

State Surgical Supply

With regard to allegations regarding Push IV's ordering, at my direction, prescription drugs and materials from an unlicensed pharmacy, I wish to provide context and an explanation. In January 2015, we attempted to order bags of normal saline from State Surgical Supply in Arkansas ("SSS"). On January 29, 2015, Mr. Auspitz received an email from SSS (see Exhibit-3) which stated in part, "Each state has different requirements and that keeps our license compliance officer on her toes. What I need is a copy of the Dr. Nevarez's Nevada State Board of Pharmacy License.... Nevada requires us to have a copy of that license on file to ship RX items. The address on the Nevada State Board of Pharmacy License is the only address we can ship RX items to." Push IV duly complied with that request, believing the pharmacy to have a better understanding of applicable law than we did. For a brief period of time, Push IV ordered normal saline from SSS, but later switched all ordering to McKesson.

After receiving the BOP's Notice in this case, I contacted SSS on June 20, 2019 to understand their licensure status. (See Exhibit 4). I had been told that SSS held a Nevada wholesaler's license with the BOP and sought verification. My most recent response from SSS was that they were checking with their "RX compliance officer," but I was assured "we are licensed in NV to sell RX items including Saline." My own license verification through the BOP website yielded no results which appeared to be related in any way to SSS. I am at a loss to explain the discrepancy, and can only explain to the BOP that we understood SSS to be operating in compliance with Nevada law, or Push IV never would have used them.

Summary

I appreciate the BOP's efforts in enforcing existing law for the benefit of the public, but I hope the Board will understand my efforts and intent to safeguard both the public interest and the integrity of the medical profession. As mentioned, I am an emergency room physician, I tried through my own due diligence to comply with all laws. However, since PUSH is not owned by a medical doctor or licensed by any state board, I believe it is best to resign my position, as I do not want to put my licenses at further risk.

July 1, 2019

Christopher Nevarez, M.D.

EXHIBIT 1

EMAILS

D. WUEST, 9/2015

From: David Wuest <dwuest@pharmacy.nv.gov>

Date: September 3, 2015 at 9:50:56 AM PDT
To: ")@yahoo.com" <c)@yahoo.com>
Subject: RE: dispensing zofran question

Doctor, thank you for your question. Could you please call me when you have a chance.

Sincerely,

Dave

J. David Wuest R.Ph.
Deputy Secretary
(775) 850-1440
dwuest@pharmacy.nv.gov

-----Original Message-----
From: Pharmacy Board
Sent: Wednesday, September 02, 2015 8:08 AM
To: David Wuest
Subject: FW: dispensing zofran question

From: Chris Nevarez [@yahoo.com]
Sent: Tuesday, September 01, 2015 4:27 PM
To: Pharmacy Board
Subject: dispensing zofran question

To whom it may concern,

My name is Dr. Christopher Nevarez. I'm currently functioning as Medical Director for PUSH IV INC here in Las Vegas, Nevada. We've been interested in adding to our provided services to include IV Zofran and / or Toradol if allowed. Admittedly, I'm not familiar with the rules or regulations of making this a reality. Could you please enlighten me or point me in the appopriate direction? As a background, the company is currently utilizing licensed nurses and medics to start IV's and administer prefabricated solutions of normal saline as a treatment for hangovers. My medical license is on file for procedures and protocols and hope to use it accordingly to guidlines to begin administering the above medications as well. Please advise.

Sincerely,

Christopher Nevarez M.D.

EXHIBIT 2

EMAILS

T. RICH, 12/2015

From: Todd Rich <trich@medboard.nv.gov>
Date: December 8, 2015 at 3:37:37 PM PST
To: "'Nevarez'" < : @yahoo.com>
Subject: RE: Medical Spa Question

Hi Dr. Nevarez:

The medical spa issue in Nevada is one that could use some clarity relative to the Nevada Revised Statutes (NRS). It has not been well defined by the Nevada Legislature, and is not defined in the Board of Medical Examiner's (Board) governing statutes, chapter 630. From the Board perspective, we are interested in ensuring that the practice of medicine (below) is only performed by licensed practitioners. Typically, medical spa's offer a variety of services, and it has been our position if these services are invasive in nature, then there needs to be physician involvement. Some of the services can be delegated, please see NAC 630.800-630.830 (below).

In respect to ownership of a medical spa, this issue in not contemplated in Chapter 630 of the NRS. However, there are some areas of the law that discuss referral of patients and accepting compensation (also below) that you may want to review. I don't know of any specific Nevada law that would not allow ownership of a medical spa by a non-licensed practitioner, but you may want to seek legal advice on the ownership question. Please feel free to call me if you have other questions.

NRS 630.020 "Practice of medicine" defined. "Practice of medicine" means:

1. To diagnose, treat, correct, prevent or prescribe for any human disease, ailment, injury, infirmity, deformity or other condition, physical or mental, by any means or instrumentality, including, but not limited to, the performance of an autopsy.
2. To apply principles or techniques of medical science in the diagnosis or the prevention of any such conditions.
3. To perform any of the acts described in subsections 1 and 2 by using equipment that transfers information concerning the medical condition of the patient electronically, telephonically or by fiber optics from within or outside this State or the United States.
4. To offer, undertake, attempt to do or hold oneself out as able to do any of the acts described in subsections 1 and 2.

NAC 630.800 "Delegating practitioner" defined. (NRS 630.130, 630.138) As used in NAC 630.800 to 630.830, inclusive, unless the context otherwise requires, "delegating practitioner" means a

person who is licensed as a physician or physician assistant and who delegates to a medical assistant the performance of a task pursuant to the provisions of NAC 630.810 or 630.820.

(Added to NAC by Bd. of Medical Exam'rs by R094-12, eff. 2-20-2013)

NAC 630.810 Delegation of tasks to medical assistant. (NRS 630.130, 630.138)

1. A delegating practitioner may delegate to a medical assistant the performance of a task if:

(a) The delegating practitioner knows that the medical assistant possesses the knowledge, skill and training to perform the task safely and properly;

(b) The medical assistant is not required to be certified or licensed to perform that task; and

(c) The medical assistant is employed by the delegating practitioner or the medical assistant and the delegating practitioner are employed by the same employer.

2. Except as otherwise provided in NAC 630.820, if a medical assistant is delegated a task which involves an invasive procedure, the delegating practitioner must be immediately available to exercise oversight in person while the medical assistant performs the task.

(Added to NAC by Bd. of Medical Exam'rs by R094-12, eff. 2-20-2013)

NAC 630.820 Remote supervision of medical assistant. (NRS 630.130, 630.138)

1. A delegating practitioner may supervise remotely a medical assistant to whom the practitioner has delegated the performance of a task if:

(a) The patient is located in a rural area;

(b) The delegating practitioner is physically located a significant distance from the location where the task is to be performed;

(c) The delegating practitioner determines that the exigent needs of the patient require immediate attention;

(d) The patient and the delegating practitioner previously established a practitioner-patient relationship; and

(e) The delegating practitioner is immediately available by telephone or other means of instant communication during the performance of the task by the medical assistant.

2. As used in this section, "rural area" means any area in this State other than Carson City or the City of Elko, Henderson, Reno, Sparks, Las Vegas or North Las Vegas.

(Added to NAC by Bd. of Medical Exam'rs by R094-12, eff. 2-20-2013)

NAC 630.830 Prohibited activities by delegating practitioner. (NRS 630.130, 630.138) A delegating practitioner retains responsibility for the safety and performance of each task which is delegated to a medical assistant. A delegating practitioner shall not:

1. Delegate a task that is not within the authority, training, expertise or normal scope of practice of the delegating practitioner;

2. Transfer to another physician or physician assistant the responsibility of supervising a medical assistant during the performance of a task unless the physician or physician assistant knowingly accepts that responsibility;

3. Authorize or allow a medical assistant to delegate the performance of a task delegated to the medical assistant to any other person; or

4. Delegate or otherwise allow a medical assistant to administer an anesthetic agent which renders a patient unconscious or semiconscious.

NRS 630.305 Accepting compensation to influence evaluation or treatment; inappropriate division of fees; inappropriate referral to health facility, laboratory or commercial establishment; charging for services not rendered; aiding practice by unlicensed person; delegating responsibility to unqualified person; failing to disclose conflict of interest; failing to initiate performance of community service; exception.

1. The following acts, among others, constitute grounds for initiating disciplinary action or denying licensure:

(a) Directly or indirectly receiving from any person, corporation or other business organization any fee, commission, rebate or other form of compensation which is intended or tends to influence the physician's objective evaluation or treatment of a patient.

(b) Dividing a fee between licensees except where the patient is informed of the division of fees and the division of fees is made in proportion to the services personally performed and the responsibility assumed by each licensee.

(c) Referring, in violation of NRS 439B.425, a patient to a health facility, medical laboratory or commercial establishment in which the licensee has a financial interest.

(d) Charging for visits to the physician's office which did not occur or for services which were not rendered or documented in the records of the patient.

(e) Aiding, assisting, employing or advising, directly or indirectly, any unlicensed person to engage in the practice of medicine contrary to the provisions of this chapter or the regulations of the Board.

(f) Delegating responsibility for the care of a patient to a person if the licensee knows, or has reason to know, that the person is not qualified to undertake that responsibility.

(g) Failing to disclose to a patient any financial or other conflict of interest.

(h) Failing to initiate the performance of community service within 1 year after the date the community service is required to begin, if the community service was imposed as a requirement of the licensee's receiving loans or scholarships from the Federal Government or a state or local government for the licensee's medical education.

2. Nothing in this section prohibits a physician from forming an association or other business relationship with an optometrist pursuant to the provisions of NRS 636.373.

NRS 439B.425 Prohibited referral of patients; exceptions; penalty.

1. Except as otherwise provided in this section, a practitioner shall not refer a patient, for a service or for goods related to health care, to a health facility, medical laboratory, diagnostic imaging or radiation oncology center or commercial establishment in which the practitioner has a financial interest.

2. Subsection 1 does not apply if:

(a) The service or goods required by the patient are not otherwise available within a 30-mile radius of the office of the practitioner;

(b) The service or goods are provided pursuant to a referral to a practitioner who is participating in the health care plan of a health maintenance organization that has been issued a certificate of authority pursuant to chapter 695C of NRS;

(c) The practitioner is a member of a group practice and the referral is made to that group

practice;

(d) The referral is made to a surgical center for ambulatory patients, as defined in NRS 449.019, that is licensed pursuant to chapter 449 of NRS;

(e) The referral is made by:

(1) A urologist for lithotripsy services; or

(2) A nephrologist for services and supplies for a renal dialysis;

(f) The financial interest represents an investment in a corporation that has shareholder equity of more than $100,000,000, regardless of whether the securities of the corporation are publicly traded; or

(g) The referral is made by a physician to a surgical hospital in which the physician has an ownership interest and:

(1) The surgical hospital is:

(I) Located in a county whose population is less than 100,000; and

(II) Licensed pursuant to chapter 449 of NRS as a surgical hospital and not as a medical hospital, obstetrical hospital, combined-categories hospital, general hospital or center for the treatment of trauma;

(2) The physician making the referral:

(I) Is authorized to perform medical services and has staff privileges at the surgical hospital; and

(II) Has disclosed the physician's ownership interest in the surgical hospital to the patient before making the referral;

(3) The ownership interest of the physician making the referral pertains to the surgical hospital in its entirety and is not limited to a department, subdivision or other portion of the hospital;

(4) Every physician who has an ownership interest in the surgical hospital has agreed to treat patients receiving benefits pursuant to Medicaid and Medicare;

(5) The terms of investment of each physician who has an ownership interest in the surgical hospital are not related to the volume or value of any referrals made by that physician;

(6) The payments received by each investor in the surgical hospital as a return on his or her investment are directly proportional to the relative amount of capital invested or shares owned by the investor in the hospital;

(7) None of the investors in the surgical hospital has received any financial assistance from the hospital or any other investor in the hospital for the purpose of investing in the hospital; and

(8) Either:

(I) The governing body of every other hospital that regularly provides surgical services to residents of the county in which the surgical hospital is located has issued its written general consent to the referral by such physicians of patients to that surgical hospital; or

(II) The board of county commissioners of the county in which the surgical hospital is located has issued a written declaration of its reasonable belief that the referral by such physicians of patients to that surgical hospital will not, during the 5-year period immediately following the commencement of such referrals, have a substantial adverse financial effect on any other hospital that regularly provides surgical services to residents of that county.

3. A person who violates the provisions of this section is guilty of a misdemeanor.

4. The provisions of this section do not prohibit a practitioner from owning and using equipment in his or her office solely to provide to his or her patients services or goods related to health care.

5. As used in this section:

(a) "Group practice" means two or more practitioners who organized as a business entity in accordance with the laws of this state to provide services related to health care, if:

(1) Each member of the group practice provides substantially all of the services related to health care that he or she routinely provides, including, without limitation, medical care, consultations, diagnoses and treatment, through the joint use of shared offices, facilities, equipment and personnel located at any site of the group practice;

(2) Substantially all of the services related to health care that are provided by the members of the group practice are provided through the group practice; and

(3) No member of the group practice receives compensation based directly on the volume of any services or goods related to health care which are referred to the group practice by that member.

(b) "Patient" means a person who consults with or is examined or interviewed by a practitioner or health facility for purposes of diagnosis or treatment.

(c) "Substantial adverse financial effect" includes, without limitation, a projected decline in the revenue of a hospital as a result of the loss of its surgical business, which is sufficient to cause a deficit in any cash balances, fund balances or retained earnings of the hospital.

Todd Rich
Deputy Executive Director
Nevada State Board of Medical Examiners
trich@medboard.nv.gov
(775) 324-9355

From: Nevarez [mailto:)@yahoo.com]
Sent: Tuesday, December 08, 2015 1:36 PM
To: Todd Rich
Cc: Chris Nevarez
Subject: Re: Medical Spa Question

Hello again Mr. Rich, your email below was very helpful indeed but I do have some follow ups.

To provide a bit of background, I'm currently medical director for an up and coming medical spa in Las Vegas. At present, we provide intravenous fluids for purposes of health maintenance, vitamin replenishments, and of course hangover recovery. I'm attempting to ensure that all boxes are checked and t's are crossed as we move forward. I joined the americanmedspa.org in hopes of fully outlying and understanding those that can and should be involved in med spas and ran across the following excerpt:

> Who can own a medical spa?
>
> Because Nevada is a "corporate practice of medicine" State, generally only (LINK) licensed physicians can own medical spas in Nevada. That means the corporate practice of medicine is only legal if conducted by a professional entity, whose shareholders, members, officers, directors and managers are all licensed Nevada physicians. This is because the statutes governing physicians could be circumvented if one or more persons who themselves do not have the requisite learning to become physicians could nevertheless form a business in whose name they could lawfully practice medicine when they do not qualify to do so as individuals. Further, a physician who performed medical services and whose payment for the services was made to a non-physician who then paid the physician would generally be considered to be fee-splitting, which is a violation of Nevada law.

Not to put it too simply, but as I understand this non licensed personnel cannot own med spas in that they cannot dictate medical policy to medical personnel. I have some current business partners who started this particular med spa concept who are not licensed medical providers and I'm working to make sure our business model isn't in violation of current Nevada law. Would this clause be circumvented if the Medical Director were an Independent Contractor to the medical spa? To put it bluntly, I didn't quite know where to start so here we are. Hopefully you can help point me in the right direction.

Sincerely,

Christopher Nevarez MD

Hello Dr. Nevarez:

The subject of medical spas is not really contemplated in the Medical Board's governing statutes. If the services include the "practice of medicine" (below), then an appropriate licensed medial practitioner needs to be involved. In regard to the corporate practice of medicine, I would refer you NRS 630.305 (also below). Please call me if you have more specific questions, and I can try to assist you. My direct number is listed below.

NRS 630.020 "Practice of medicine" defined. "Practice of medicine" means:

1. To diagnose, treat, correct, prevent or prescribe for any human disease, ailment, injury, infirmity, deformity or other condition, physical or mental, by any means or instrumentality, including, but not limited to, the performance of an autopsy.
2. To apply principles or techniques of medical science in the diagnosis or the prevention of any such conditions.
3. To perform any of the acts described in subsections 1 and 2 by using equipment that transfers information concerning the medical condition of the patient electronically, telephonically or by fiber optics from within or outside this State or the United States.
4. To offer, undertake, attempt to do or hold oneself out as able to do any of the acts described in subsections 1 and 2.

NRS 630.305 Accepting compensation to influence evaluation or treatment; inappropriate division of fees; inappropriate referral to health facility, laboratory or commercial establishment; charging for services not rendered; aiding practice by unlicensed person; delegating responsibility to unqualified person; failing to disclose conflict of interest; failing to initiate performance of community service; exception.

1. The following acts, among others, constitute grounds for initiating disciplinary action or denying licensure:

(a) Directly or indirectly receiving from any person, corporation or other business organization any fee, commission, rebate or other form of compensation which is intended or tends to influence the physician's objective evaluation or treatment of a patient.

(b) Dividing a fee between licensees except where the patient is informed of the division of fees and the division of fees is made in proportion to the services personally performed and the responsibility assumed by each licensee.

(c) Referring, in violation of NRS 439B.425, a patient to a health facility, medical laboratory or commercial establishment in which the licensee has a financial interest.

(d) Charging for visits to the physician's office which did not occur or for services which were not rendered or documented in the records of the patient.

(e) Aiding, assisting, employing or advising, directly or indirectly, any unlicensed person to engage in the practice of medicine contrary to the provisions of this chapter or the regulations of the Board.

(f) Delegating responsibility for the care of a patient to a person if the licensee knows, or has reason to know, that the person is not qualified to undertake that responsibility.

(g) Failing to disclose to a patient any financial or other conflict of interest.

(h) Failing to initiate the performance of community service within 1 year after the date the community service is required to begin, if the community service was imposed as a requirement of the licensee's receiving loans or scholarships from the Federal Government or a state or local government for the licensee's medical education.

2. Nothing in this section prohibits a physician from forming an association or other business relationship with an optometrist pursuant to the provisions of NRS 636.373.

Thank you.

Todd Rich
Deputy Executive Director
Nevada State Board of Medical Examiners

trich@medboard.nv.gov
(775) 324-9355

EXHIBIT 3

EMAILS

STATE SURGICAL SUPPLY, 1/2015

From: "Ken Thomas" <KThomas@StateSurgicalSupply.com>
Date: January 29, 2015 at 8:45:07 AM PST
To: "'Noah Auspitz'" <[redacted]pushlv.com>
Subject: RE: Nevada Licensure - Christopher Nevarez M.D.

Good morning Noah,
I apologize for the license request confusion. Each state has different requirements and that keeps our license compliance officer on her toes.
What I need is a copy of the Dr. Nevarez's Nevada State Board of Pharmacy License. That license expires every two years. Nevada requires us to have a copy of that license on file to ship RX items. The address on the Nevada State Board of Pharmacy License is the only address we can ship RX items to. I hope this information is not a surprise to you.
Below it the public license information off of the Nevada State Board of Pharmacy website. I will need an actual copy of it. Let me know if I can help.

Best regards,

Ken Thomas
Arkansas Surgical Supply- State Surgical Supply
StateSurgicalSupply.com
479-756-6871
800-756-6871

From: Noah Auspitz [mailto:[redacted]pushlv.com]

Sent: Wednesday, January 28, 2015 5:45 PM
To: Ken Thomas
Subject: Fwd: Nevada Licensure - Christopher Nevarez M.D.

Hey Ken see below...

Begin forwarded message:

From: Chris Nevarez
<[redacted]@yahoo.com>
Subject: Fwd: Nevada Licensure - Christopher Nevarez M.D.
Date: January 26, 2015 4:13:29 PM PST
To: Noah Auspitz <Noah@pushlv.com>

Sent from my iPhone

Begin forwarded message:

From: "Kristi L. Stewart"
<klsnsbme@medboard.nv.gov>
Date: January 26, 2015 at 2:38:27 PM PST
To: "'[redacted]@yahoo.com'"
<[redacted]@yahoo.com>
Subject: Nevada Licensure - Christopher Nevarez M.D.

Good afternoon Dr. Nevarez,

Your license is valid until 06/30/2015. You may refer to the back of your wallet card (license) or you may view your information at:
http://medboard.nv.gov/Verification/

Sincerely,

Kristi Stewart
License Specialist
Nevada State Board of Medical Examiners
P.O. Box 7238
Reno, NV 89510-7238
Ph. 775-688-2559 x228
Fax 775-688-2551
www.medboard.nv.gov

www.medboard.nv.gov Please consider the environment before printing this email

All the best,

EXHIBIT 4

EMAILS

STATE SURGICAL SUPPLY, 6/2019

---------- Forwarded message ---------
From: <KThomas@arkansassurgicalsupply.com>
Date: Wed, Jun 26, 2019 at 2:42 PM
Subject: RE: Wholesale license
To: christopher nevarez < [redacted] @gmail.com>

Dr Nevarez,

I forwarded your email to our RX compliance officer to see what licensed you will need from us. It is the end of day here so it will be tomorrow until I have the information. I assure you we are licensed in NV to sell RX items including Saline.

Best regards,

Ken Thomas

Arkansas Surgical Supply - State Surgical Supply

Office 479-756-6871 or 800-756-6871

From: christopher nevarez < [redacted] d@gmail.com>

Sent: Wednesday, June 26, 2019 4:34 PM
To: KThomas@arkansassurgicalsupply.com
Subject: Fwd: Wholesale license

Below is the forwarded email from my sent mail folder. I hope you may be able to assist. Have a pleasant rest of the day.

I have since found our email correspondence in which I forwarded copies of my CS license as well as my Nevada state medical license. I'm confused as to where they see a discrepancy and hope your wholesale license may provide some clarification for them.

Sincerely,

Christopher Nevarez MD

---------- Forwarded message ---------
From: **christopher nevarez** < d@gmail.com>
Date: Thu, Jun 20, 2019 at 10:32 AM
Subject: Wholesale license
To: <kthomas@statesurgicalsupply.com>

Mr. Thomas,

Hope this email finds you well. I spoke with one of your representatives at the number provided on your website, John I believe, and he directed my inquiry to you. My name is Dr Christopher Nevarez and I'm medical director for PUSH IV in Las Vegas. I've recently run into some difficulties with the Nevada board of pharmacy regarding our previous transaction. They're alleging that you do not have a license to sell saline (which as I recall is the only item we would have purchased from you) in Nevada. Your colleague mentioned your company possesses a wholesale license and are permitted to sell to licensed providers such as myself. Is this correct and, if so, may I request a copy of your wholesale license for use in my defense?

Sincerely,
Christopher Nevarez
Sent from my iPhone

5B

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NOS. 17-100-CS-S**
	)	
Petitioner,	)	**NOTICE OF INTENDED ACTION**
v.	)	**AND ACCUSATION**
	)	
DOUGLAS ROSS, M.D.,	)	
Certificate of Registration No. CS10138,	)	
	)	
Respondent.	/	

J. David Wuest, 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 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Douglas Ross, M.D., Certificate of Registration No. CS10138 ("Dr. Ross") held a Board-issued controlled substance registration.

FACTUAL ALLEGATIONS

II.

In October 2017, Respondent Dr. Ross was the medical director of Infuze LV, LLC ("Infuze LV").

III.

While Dr. Ross was Infuze LV's medical director, the Board received consumer complaints alleging that under Dr. Ross's direction, Infuze LV allowed registered nurses ("RNs") and licensed paramedics (collectively "Non-practitioner Staff Members") to access,

possess and administer dangerous drugs to patients by intravenous ("IV") and intramuscular injections.

IV.

The Board's investigation produced evidence to substantiate those claims.

V.

Dr. Ross allowed Infuze LV's Non-Practitioner Staff to access, possess and control Infuze LV's inventory of dangerous drugs without a licensed practitioner present.

VI.

Dr. Ross and Infuze LV allowed Non-practitioner Staff to provide IV therapy, injections and other medical procedures where the patient had not been examined by a practitioner and therefore did not have a *bona fide* relationship with the practitioner who authorized the treatment.

VII.

Under Dr. Ross's direction, Infuze LV's Non-practitioner Staff Members accessed and possessed the clinic's inventory of dangerous drugs and provided supplies of dangerous drugs to Non-Practitioner Staff Members without a practitioner on site, without a practitioner's direct supervision, before Dr. Ross or any other practitioner examined the patient, and before there was a patient-specific and medication-specific written order for the patient and/or the medication.

VIII.

Dr. Ross allowed Infuze LV's Non-practitioner Staff Members to transport dangerous drugs without a patient-specific and medication-specific order.

IX.

Dr. Ross frequently had no contact with and did not examine the patient to establish a *bona fide* therapeutic relationship with the patient until after one of Infuze LV's Non-Practitioner Staff Members transported the dangerous drugs in his/her possession to the patient's location.

X.

For off-site medical treatment, once a Non-practitioner Staff Member arrived at the patient's location, the RN or paramedic would examine the patient and discuss why an IV or injection would be beneficial to the patient.

XI.

The RN would then communicate his/her assessment of the patient to Dr. Ross by telephone or text, by which Dr. Ross would then approve the medication by text.

XII.

Through that exam process, Dr. Ross often did not speak or communicate directly with the patient.

XIII.

Infuze LV and its Non-practitioner Staff Members often provided medical treatment to patients at its physical location when Dr. Ross was not on site.

APPLICABLE LAW

XIV.

No person may possess a dangerous drug in Nevada without specific statutory authority to do so. *See* NRS 454.213, NRS 454.316, NRS 454.321.

XV.

A practitioner can give a registered nurse limited authority to possess and administer dangerous drugs without the practitioner onsite by way of NRS 454.213(1)(c), which says in relevant part:

> a drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, *or pursuant to a chart order, for administration to a patient at another location.*

NRS 454.213(1)(a)(*emphasis added*); *see also* NRS 639.100.

XVI.

Chart orders must be written (NRS 454.223) and are patient-specific and medication-specific.[1]

XVII.

"Except as otherwise specifically provided, every person who violates any provision of NRS 454.181 to 454.371, inclusive, is guilty of a misdemeanor." NRS 454.356.

XVIII.

A practitioner must first establish a *bona fide therapeutic relationship* with a patient by examination before he or she can determine that a medication is medically necessary and direct and/or authorize an RN to possess and administer a dangerous drug on-site or issue a chart order for off-site administration of a dangerous drug to treat the patient's medical condition. *See* NAC 639.945(1)(o) and NRS 454.213(1)(a).

XIX.

> [A] bona fide therapeutic relationship between the patient and practitioner shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics . . . by the practitioner within the 6 months immediately preceding the date the practitioner . . . prescribes a drug to the patient and, as a result of the examination, the practitioner diagnosed a condition for which a given drug therapy is prescribed.

NRS 639.945(3).

XX.

> An outsourcing facility that is engaged in the compounding of sterile drugs in this State [Nevada] or for shipment into this State shall:
>
> 1. Obtain a license from the Board as a manufacturer in accordance with NRS 639.100 and 639.233;

---

[1] *See* NRS 639.004 "Chart order" means an order entered on the chart of a patient in a hospital, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and

3. Comply with all the requirements of 21 U.S.C. § 353b.

NAC 639.6915

XXI.

"Supplying . . . medicines, substances or devices which are legally sold in pharmacies or by wholesalers, 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." NAC 639.945(1)(g).

XXII.

A licensee "[p]erforming any of his or her duties as the holder of a license, certificate or registration issued by the Board . . . in an incompetent, unskillful or negligent manner" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(i).

XXIII.

"Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration" constitutes "unprofessional conduct and conduct contrary to the public interest." NAC 639.945(1)(k).

XXIV.

The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

XXV.

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).

XXVI.

Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(12).

FIRST CAUSE OF ACTION
Unlawful Access and Possession of Dangerous Drugs - Statutory Violations

XXVII.

By allowing Infuze LV's Non-practitioner Staff Members to operate Infuze LV and to use his authority as a practitioner to obtain, access, possess and/or store dangerous drugs when he was not on site, before he examined the patient (or without an examination), before he wrote a patient-specific order and without his direct supervision, Dr. Ross violated, or assisted and abetted Infuze LV's staff in violating, NRS 454.213(1), NRS 454.316 and/or NRS 454.356.

SECOND CAUSE OF ACTION
Unlawful Access and Possession of Dangerous Drugs – Unprofessional Conduct

XXVIII.

By allowing Infuze LV's staff, none of whom were practitioners and none of whom were licensed to possess or prescribe dangerous drugs, to operate Infuze LV and/or to obtain, access, possess and store dangerous drugs when he was not on site, before he examined the patient and before he wrote a patient-specific order, Dr. Ross engaged, or assisted and abetted Infuze LV's staff to engage, in unprofessional conduct as defined in NAC 639.945(1)(g), (i), and (k).

THIRD CAUSE OF ACTION
Unlawful Administration of Dangerous Drugs – No Bona Fide Therapeutic Relationship and No Authority to Determine Medical Necessity

XXIX.

By authorizing Infuze LV's Non-practitioner Staff, none of whom were licensed practitioners, to use his authority to operate Infuze LV, to administer a dangerous drug to patients who had not been examined by a practitioner, when he did not have a *bona fide*

therapeutic relationship and for whom he had not diagnosed or determined that a dangerous drug was medically necessary, Dr. Ross violated, and/or aided and abetted Infuze LV's staff in violating Nevada law, including NRS 454.221(1). He also acted unprofessionally. *See* NAC 639.945(1)(k) and (o).

XXX.

For the violations and conduct alleged in paragraphs II through XXIX above, Dr. Ross's Controlled Substance Registration, Certificate of Registration No. CS10138 is subject to discipline pursuant to NRS 453.236(1)(d), NRS 453.241(1), NRS 639.210(4) and (12) and/or NRS 639.255.

XXXI.

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

Signed this 13th day of June 2019.

J. David Wuest, R.Ph., 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. NRS 233B.127(3). 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. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 17-100-CS-S**
	)	
Petitioner,	)	
v.	)	
	)	**STATEMENT TO THE**
DOUGLAS ROSS, M.D.,	)	**RESPONDENT**
Certificate of Registration No. CS10138,	)	**NOTICE OF INTENDED ACTION**
	)	**AND ACCUSATION**
Respondent.	/	**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 and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, 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 show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). 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. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 17, 2019, 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.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 13th day of June, 2019.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 13th day of June, 2019, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

DOUGLAS ROSS, MD
2481 W HORIZON RIDGE PKWY #100
HENDERSON, NV 89052

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

STATE OF NEVADA BOARD OF PHARMACY, **Petitioner,** **-vs-** **DOUGLAS ROSS, M.D.,** **Certificate of Registration No. CS10138** **Respondent.**	**CASE NO. 17-100-CS-S** **ANSWER TO NOTICE OF INTENDED ACTION AND ACCUSATION**

DOUGLAS ROSS, M.D., by and through his attorneys Maria Nutile, Esq. and Bridget Kelly, Esq. of the law firm Nutile Law, and in answer to the Notice of Intended Action and Accusation in the above referenced matter, filed on June 13, 2019 upon permission from the Nevada State Board of Pharmacy ("Board"), admits and denies as follows:

1. Answering Paragraphs I, II, III Respondent admits the allegations contained therein.
2. Answering Paragraphs VI, VII, VIII, IX, XII, XIII, XXVII, XXVIII, and XXIX, Respondent denies the allegations contained therein.
3. Answering Paragraphs IV, X, XI, Respondent is without sufficient knowledge upon which to base a belief as to the truth of the allegations contained therein, and therefore denies each and every allegation contained therein.
4. Answering Paragraphs V, XXX, XXXI, and Paragraphs XIV through XXVI, Respondent states these Paragraphs require no response.

DATED this 3rd day of July 2019.

NUTILE LAW

MARIA NUTILE, ESQ.
Nevada Bar No. 7847
BRIDGET KELLY, ESQ.
Nevada Bar No. 14388
NUTILE LAW
7395 S. PECOS RD.
SUITE 103
LAS VEGAS, NV 89120
(702) 307-4880
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bridget@nutilelaw.com
maria@nutilelaw.com
Attorneys for Respondent

CERTIFICATE OF SERVICE

I hereby certify that I am an employee of Nutile Law and that on the 3rd day of July 2019, a copy of RESPONDENT'S ANSWER TO NOTICE OF INTENDED ACTION AND ACCUSATION, CASE NO. 17-100-CS-S with all Exhibits thereto, was placed into the hands of the United States Postal Service, postage prepaid on the date listed herein, addressed as follows:

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste. 206
Reno, NV 89521

A copy was also emailed to S. Paul Edwards, General Counsel for the Board, at pedwards@pharmacy.nv.gov

Dated this 3rd day of July 2019.

An Employee of Nutile Law

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DOUGLAS ROSS, M.D., Certificate of Registration No. CS10138, Respondent.	)	CASE NO. 17-100-CS-S ANSWER AND NOTICE OF DEFENSE

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").

None.

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

Please see attached statement.

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 3 day of ~~June~~ July 2019.

DOUGLAS ROSS, M.D.

Respondent Statement
Case No. 17-100-CS-S
Douglas Ross, M.D.

In answer to the Notice of Intended Action and Accusation, I deny the allegations against me in the Notice.

I have been the Medical Director of Infuze, LLC ("Infuze") since it opened in 2015. I am also a Fellow of the American College of Emergency Physicians and have been licensed to practice in Nevada since 2000.

My intent in establishing and operating Infuze has always been to provide high-quality patient care in accordance with state and federal law and professional ethics. Through the course of this investigation by the Board of Pharmacy ("BOP"), I learned that my initial understanding of proper procedure in providing infusion services was not entirely accurate, though not for lack of due diligence on my part. I have also learned there is a high degree of confusion and ambiguity on the part of both infusion practices and regulatory agencies responding to a relatively new practice model.

As I had stated in my initial response to the BOP in this matter dated March 14, 2018 ("Initial Response"), Infuze ceased utilizing emergency medical technicians ("EMTs") to provide any services, other than when acting as medical assistants ("MAs") in the clinic setting with appropriate supervision. This change was in immediate response to being informed by the BOP in early 2018 during its investigation that EMTs are not authorized to provide infusion services outside of EMS duty. As discussed in my Initial Response, neither my legal due diligence in launching Infuze (including a discussion with a physician-director of the Southern Nevada Health District) nor my first-hand experience with EMTs as an emergency physician, informed me that off-duty EMTs could not independently perform any concierge infusion visits. Additionally, many active Senior Paramedics working for Las Vegas Fire, Henderson Fire, Boulder City Fire, Community Ambulance, and AMR, with whom I had discussed this issue, were similarly ignorant as to their own scope of authority when not on EMS duty. Nonetheless, I modified Infuze's operations immediately upon notification of its non-compliant utilization of EMTs.

Similarly, Infuze ceased permitting registered nurses ("RNs") to transport infusion supplies to any patients, prior to a practitioner's assessment and order, immediately upon learning of this requirement. A Regulatory Interpretation by BOP General Counsel S. Paul Edwards dated May 23, 2018 as published by a third-party website[1] (see Exhibit 1, "Interpretation"), clarifies legal limitations on an RN's possession of prescription medication for off-site administration. I find it noteworthy that this issue has been ambiguous enough in the Las Vegas healthcare market to spawn an entire "Bad RN" website to explain and warn RN's of practice limitations related to

[1] https://www.badrn.com/regulatory-letters, accessed July 1, 2019.

July 3, 2019

Douglas Ross, M.D.

mobile infusion services, yet no guidance on this issue could be found on the BOP website as of the date of this statement. I know I am not the only practice trying to navigate the murky legal compliance related to increasingly popular outpatient and mobile IV infusion, and it is disappointing that professional guidance should be so difficult to find.

As stated in my Initial Response, my medical practice is located immediately adjacent to the Infuze clinic, so I have been able to provide personal oversight and supervision as Medical Director since Infuze began. I have also actively and consistently provided telehealth assessments for Infuze's concierge services. Where our proactive efforts have failed, we have reacted immediately to new guidance and information, and adjusted policies, procedures, and personnel as necessary for compliance. Currently, I or a physician's assistant or a nurse practitioner perform a telehealth assessment of each patient prior to dispatching an RN to a patient preferred site, and Infuze RN's only carry those medications and supplies necessary to fulfill an order for a *bona fide* patient. Although Infuze's practice model has evolved and adapted in the interests of compliance, at no point did Infuze compromise patient safety or quality of care

I respectfully request that the charges against me be dismissed.

Douglas Ross, M.D.

June___, 2019

EXHIBIT 1

Regulatory Interpretation

Nevada State Board of Pharmacy

431 W. Plumb Lane• Reno, NV 89509
(775) 850-1440 • 1-800-364-2081• FAX (775) 850-1444
E-mail: pedwards@pharmacy.nv.gov • Web Page: bop.nv.gov

May 23, 2018

Jason Burke, M.D.
Hangover Heaven, LLC
3281 S. Highland Dr., #806
Las Vegas, Nevada 89109

Dear Dr. Burke:

I am responding on behalf of the Nevada State Board of Pharmacy (Board) to two "scenarios" you presented in your January 24, 2018 *Petition for Regulatory Interpretation to the Nevada Board of Pharmacy.* Those scenarios can be reduced to two questions, as indicated in your April 6, 2018 email to the Board. The plain language of existing statutes answer both of those questions such that no Board interpretation is necessary. Those statutes give practitioners general authority to possess and administer prescription medications in conformity with the applicable standard of care. A registered nurse[1] (RN), however, may possess a prescription medication for off-site administration only pursuant to an existing patient-specific chart order.

Legal Framework:

No person may possess a controlled substance or a dangerous drug (collectively a prescription medication) in Nevada without specific statutory authority to do so.[2] The Nevada Legislature granted practitioners[3] that authority in NRS chapters 453 and 454.[4] RNs do not enjoy such broad authority.

---

[1] NRS 632.019 "Registered nurse" means a person who is licensed to practice professional nursing.
[2] *See* NRS 453.336, NRS 453.338, NRS 454.316, NRS 454.321.
[3] NRS 454.00958 Practitioner" means:
1. A physician, dentist, veterinarian or podiatric physician who holds a valid license to practice his or her profession in this State.
2. A pharmacy, hospital or other institution licensed or registered to distribute, dispense, conduct research with respect to or to administer a dangerous drug in the course of professional practice in this State.
3. When relating to the prescription of poisons, dangerous drugs and devices:
(a) An advanced practice registered nurse who holds a certificate from the State Board of Pharmacy permitting him or her so to prescribe; or
(b) A physician assistant who holds a license from the Board of Medical Examiners and a certificate from the State Board of Pharmacy permitting him or her so to prescribe.
4. An optometrist who is certified to prescribe and administer dangerous drugs pursuant to NRS 636.288 when the optometrist prescribes or administers dangerous drugs which are within the scope of his or her certification.
[4] *See* NRS 453.375(1)(a); NRS 454.213(1)(a).

Regarding controlled substances, NRS chapter 453 states in relevant part:

> 1. A controlled substance may be possessed and administered by the following persons:
>
> (a) A practitioner.
>
> (b) A registered nurse licensed to practice professional nursing or licensed practical nurse, *at the direction* of a physician, physician assistant, dentist, podiatric physician or advanced practice registered nurse, or *pursuant to a chart order*, for administration to a patient at another location.
>
> . . . .

NRS 453.375(1)(a) and (b) (*emphasis added*). Similarly, as to dangerous drugs, NRS chapter 454 says:

> 1. A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by:
>
> (a) A practitioner.
>
> . . . .
>
> (c) Except as otherwise provided in paragraph (d), a registered nurse licensed to practice professional nursing or licensed practical nurse, *at the direction of* a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, *or pursuant to a chart order*, for administration to a patient at another location.
>
> . . . .

NRS 454.231(1)(a) and (c) (*emphasis added*).

By way of those statutes, the Nevada Legislature gave practitioners general authority to possess and administer prescription medications.[5] That authority is broad such that a practitioner can possess and maintain an inventory of prescription medications for the future needs of his or her practice.[6]

Conversely, the Legislature used qualifying language to describe instances where a RN may possess and administer a prescription medication.[7] A RN may possess and administer a prescription medication only "at the direction" of a practitioner, which usually occurs in a facility setting where the practitioner is located. A RN may also possess and administer a prescription medication "pursuant to a chart order, for administration to a patient at another

[5] *See* NRS 453.375(1)(a); NRS 454.213(1)(a).
[6] *Id.*
[7] NRS 453.375(1)(b); NRS 454.213(1)(c).

location."[8] Chart orders are patient-specific and medication-specific.[9] The Legislature did not grant RNs authority to possess a prescription medication (or an inventory of prescription medications) absent an existing chart order in anticipation of a yet-to-be-written chart order.

As with any prescription medication, a practitioner must first establish a bona fide therapeutic relationship with the patient before directing a RN to possess and administer a prescription medication on-site or issuing a chart order for off-site administration.[10] "[A] bona fide therapeutic relationship between the patient and practitioner shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics . . . by the practitioner within the 6 months immediately preceding the date the practitioner . . . prescribes a drug to the patient and, as a result of the examination, the practitioner diagnosed a condition for which a given drug therapy is prescribed."[11]

From that legal framework the two "scenarios" or questions you present in your Petition may be analyzed.

Scenario 1:

Your Scenario 1 asks whether, after establishing a bona fide therapeutic relationship with the patient, the practitioner has to physically give any prescription medication the practitioner ordered through a chart order to the RN for off-site administration to the patient?

Response to Scenario 1:

Yes, a RN must receive a prescription medication for off-site administration pursuant to a chart order directly from a practitioner. A RN does not have authority to possess a prescription medication that is not specifically ordered in an existing chart order.

Scenario #2:

The second scenario presented in your Petition asks whether a RN may keep medications at home or in the car in preparation for going out on house calls.

---

[8] *Id.*

[9] *See* NRS 639.004 "Chart order" means an order entered on the chart of a patient in a hospital, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

[10] *See* NAC 639.945(1)(o).

[11] NRS 639.945(3).

Response to Scenario #2:

No. A RN may possess a prescription medication "for administration to a patient at another location" "pursuant to a chart order."[12] The statutes do not authorize a RN to possess an inventory of a prescription medication without a chart order. If an RN had access to or possessed a prescription medication without a chart order for that medication, the RN would possess the prescription medication unlawfully and could be found criminally liable.[13]

Finally, it should be noted that a RN, after administering a prescription medication to a patient pursuant to chart order, may not leave any prescription medication with the patient, even if the RN anticipates making a house call to the patient in the future. Leaving medication with the patient constitutes dispensing,[14,15] which NRs are not authorized to do.[16]

You may access the statutes cited herein by way of the Board's website at bop.nv.gov, or you may request a copy from my office.

Sincerely,

S. PAUL EDWARDS, ESQ.
General Counsel
Nevada State Board of Pharmacy

[12] NRS 453.375(1)(b); NRS 454.213(1)(c).
[13] *See* NRS 453.336, NRS 453.338, NRS 454.316, NRS 454.321.
[14] NRS 453.056 "Dispense" defined.
1. Except as limited by subsection 2, "dispense" means to deliver a controlled substance to an ultimate user, patient or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.
2. The term does not include the furnishing of a controlled substance by a hospital pharmacy for inpatients.
[15] NRS 454.211 "Dispense" defined.
1. "Dispense" means the furnishing of a dangerous drug in any amount greater than that which is necessary for the present and immediate needs of the ultimate user.
2. The term does not include the furnishing of a dangerous drug by a hospital pharmacy for inpatients.
[16] NRS 453.377, NRS 454.215.

5C

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-083-CS-N**
	)	
Petitioner,	)	
v.	)	
	)	**NOTICE OF INTENDED ACTION**
ERIC MARTIN MATH, MD,	)	**AND ACCUSATION**
Certificate of Registration No. CS04598,	)	
	)	
Respondent.	)	

J. David Wuest, 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 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Eric Martin Math, MD (Math), held a Nevada Controlled Substance Registration, Certificate No. CS04598, issued by the Pharmacy Board.

FACTUAL ALLEGATIONS

II.

On June 3, 2019, Math surrendered his DEA Certificate of Registration No. BM4705616 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause" (DEA Surrender for Cause).

III.

By executing the DEA Surrender for Cause, Math acknowledged in pertinent part the following:

> In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certification of Registration.

IV.

On or about June 4, 2019, Board staff notified Math that his surrender of DEA Certificate of Registration No. BM4705616 for cause operated as an immediate suspension of his Certificate of Registration No. CS04598 with the Board pursuant to NRS 639.2107.

APPLICABLE LAW

V.

The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

VI.

The surrender of a registration to the Drug Enforcement Administration by a practitioner operates as an immediate suspension of a registration issued by the Board pursuant to NRS Chapter 453 to possess, administer, prescribe or dispense controlled substances. NRS 639.2107.

VII.

Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

VIII.

Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

FIRST CAUSE OF ACTION

IX.

By failing to comply with the Federal requirements pertaining to controlled substances, Math committed an act that would render his Nevada Controlled Substance Registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

SECOND CAUSE OF ACTION

X.

By surrendering his DEA Certificate of Registration No. FM2307468 for cause, the suspension of Math's Nevada Controlled Substance Registration, Certificate No. CS04598 pursuant to NRS 639.2107 is subject to review by the Board pursuant to NRS 453.236(1) and NRS 639.255(1)(c).

THIRD CAUSE OF ACTION

XI.

By failing to comply with the Federal requirements pertaining to controlled substances, Math is subject to discipline pursuant to NRS 639.210(11) and/or (12), and NRS 639.255.

XII.

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

Signed this 12th day of July, 2019.

J. David Wuest, R.Ph., 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. NRS 233B.127(3). 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. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-083-CS-N**
	)	
Petitioner,	)	
v.	)	
	)	**STATEMENT TO THE**
ERIC MARTIN MATH, MD,	)	**RESPONDENT**
Certificate of Registration No. CS04598,	)	**NOTICE OF INTENDED ACTION**
	)	**AND ACCUSATION**
Respondent.	/	**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 and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, 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 show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). 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. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 4, 2019, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of July, 2019.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-083-CS-N**
	)	
Petitioner,	)	
v.	)	**ANSWER AND NOTICE**
	)	**OF DEFENSE**
ERIC MARTIN MATH, MD,	)	
Certificate of Registration No. CS04598,	)	
	)	
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 July, 2019.

ERIC MARTIN MATH, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2019, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Eric Math, MD
6580 Mahogany Ridge Drive
Reno, NV 89523

SHIRLEY HUNTING

RETURN OF SERVICE

STATE OF NEVADA)
ss.
COUNTY OF WASHOE)

I HEREBY certify and return that I received the within Notice of Intended Action, Statement to the Respondent Notice of Intended Action and Accusation Right to Hearing, Answer and Notice of Defense, and Suspension of Certificate of Registration No. CS04598 on the 31st day of July, 2019 and that I personally served the same upon Front desk receptionist Itzel Arnate at the law office of David Huston, 432 Court Street, Reno, NV 89501, a person at least eighteen years of age, at law office of David Huston on the 31st day of July, 2019.

Signature

Joseph J. Depczynski
Name (print)

SUBSCRIBED AND SIGNED before me

this 31st day of JULY, 2019

by JOSEPH J. DEPCZYNSKI.

NOTARY PUBLIC

SHIRLEY LOWERY-HUNTING
Notary Public - State of Nevada
Appointment Recorded in Washoe County
No: 13-10953-2 - Expires May 24, 2021

NEVADA STATE BOARD OF PHARMACY
OFFICE OF THE GENERAL COUNSEL
WRITER'S DIRECT DIAL: (775) 850-1440 • E-MAIL: bkandt@pharmacy.nv.gov • FAX: (775) 850-1444

June 4, 2019

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO: emath@renown.org

Eric Martin Math, MD
5538 Longley Lane – Suite B
Reno, NV 89511

Re: ***Suspension of Certificate of Registration No. CS04598***

Dear Dr. Math:

The Nevada State Board of Pharmacy (Board) has been notified by the U.S. Drug Enforcement Administration that you surrendered your DEA Certificate of Registration No. BM4705616 on June 3, 2019 (documentation enclosed).

Please be advised that pursuant to NRS 639.2107 your surrender of your DEA registration operates as an immediate suspension of your Certificate of Registration No. CS04598 with the Board. Furthermore, your access to the Nevada Prescription Monitoring Program (PMP) database is terminated effective immediately since you are no longer authorized to access the PMP pursuant to NRS 453.221.

You may request a hearing before the Board to contest the suspension of your registrations by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Please be aware that the forgoing does not preclude a formal investigation or filing of an accusation pursuant to NRS 639.241. If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

9171 9690 0935 0157 4990 51

U. S. Department of Justice - Drug Enforcement Administration

SURRENDER FOR CAUSE OF DEA CERTIFICATE OF REGISTRATION

DEA USE ONLY

File No.

In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list I chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certificate of Registration.

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration.

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other activities with controlled substances or list I chemicals.

With the understanding that I am not required to surrender my DEA Certificate of Registration, I freely and under no duress, implied or expressed, execute this document and choose to take the action described herein.

NAME OF REGISTRANT *(Print)*	ADDRESS OF REGISTRANT
Eric Martin Math, M.D.	5538 Longley Ln. Ste B Reno, NV 89511
DEA REGISTRATION NO.	
BM4705616	
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL	DATE
[signature] MD	6/3/19

WITNESSES TO REGISTRANT'S SIGNATURE

NAME AND DATE	TITLE
[signature], 6/3/19	Special Agent
NAME AND DATE	TITLE
[signature] 6/3/19	Special Agent

PRIVACY ACT

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (21 U.S.C. 821).
PURPOSE: Permit surrender for cause of DEA Certificate of Registration.
ROUTINE USES: The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of customers and practitioners.
EFFECT: Submission of this information is voluntary. There is no effect on the individual if not provided.

5D

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NOS. 18-082-RPH-S**
	)	**18-082-PH-S**
Petitioner,	)	**18-131-RPH-S**
v.	)	**18-131-PH-S**
	)	
EGHOMWARE IGBINOVIA (AKA JERRY IGBINOVIA), Certificate of Registration No. 16316, and	)	**NOTICE OF INTENDED ACTION AND ACCUSATION**
	)	(Consolidated Cases)
ACRX SPECIALTY PHARMACY, Certificate of Registration No. PH03673,	)	
	)	
Respondents.	)	

J. David Wuest, 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 622A.300(1) and/or NRS 639.241.

JURISDICTION

1.

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 EGHOMWARE IGBINOVIA (aka Jerry Igbinovia) (Igbinovia), Certificate of Registration No. 16316, was a pharmacist registered with the Board, and Respondent ACRX SPECIALTY PHARMACY (ACRX), Certificate of Registration No. PH03673, located at 3204 Soaring Gulls #101, Las Vegas, Nevada was a pharmacy licensed by the Board. At times Igbinovia and ACRX are referred to collectively herein as "Respondents."

FACTUAL ALLEGATIONS

2.

At the time of the events alleged herein, Respondent Igbinovia owned and operated ACRX.

3.

Igbinovia was ACRX's managing pharmacist/pharmacist-in-charge and the only pharmacist working full time at ACRX.

Patient Complaint that ACRX Dispensed Expired Medication

4.

On August 23, 2018, ACRX dispensed two vials of human chorionic gonadotropin (HCG) to patient C.B. It designated and labelled them as Prescription No. 400989.

5.

Each of those two vials was marked with a beyond use date (BUD) of July 22, 2018.

6.

Both vials of HCG that ACRX dispensed to C.B. on August 23, 2018, were expired at the time that ACRX dispensed them.

7.

Neither of the vials of HCG that ACRX dispensed to C.B. were frozen when ACRX dispensed them.

8.

ACRX did not include instructions on either vial to freeze the product or to keep it frozen.

9.

The label on each vial of HCG that ACRX dispensed to C.B. stated "Refrigerate" and "Store in Refrigerator".

10.

Both of the vials of compounded HCG that ACRX dispensed to C.B. on August 23, 2018, were from a batch of HCG that Igbinovia compounded on June 7, 2018 and designated as Lot No. 06072018@12.

11.

Igbinovia assigned a 45-day BUD of July 22, 2018, to each of the vials that ACRX dispensed to C.B.

12.

Respondents should have assigned a three-day (3-day) BUD to each of the vials from Lot No. 06072018@12 because the product was refrigerated and Respondents did not have documentation of stability and sterility testing to support a BUD of more than three days.

13.

As of August 23, 2018, Respondents had not conducted stability or sterility testing on the HCG product that ACRX dispensed to C.B. They did not have documentation to support the 45-day BUD they assigned to the two vials of HCG that ACRX dispensed to C.B.

14.

During the investigation of C.B.'s complaint, a Board Investigator requested sales records for prescriptions filled with vials from Lot No. 06072018@12. Respondents did not provide accurate records for that batch.

15.

The names of 17 patients appeared on the sales records that Respondents provided for Lot No. 06072018@12. Patient C.B.'s name was not among those 17 names. The records for Prescription No. 400989, however, indicate the expired HCG vials that Respondents dispensed to C.B. came from Lot No. 06072018@12.

16.

ACRX assigned inconsistent BUDs to the vials it dispensed from Lot No. 06072018@12. ACRX's records show that vials of HCG from that batch were given various BUDs as follows:

07/22/2018 – ACRX dispensed vials with this BUD to 2 patients.

07/23/2018 – ACRX dispensed vials with this BUD to 4 patients.

07/28/2018 – ACRX dispensed vials with this BUD to 2 patients.

07/29/2018 – ACRX dispensed vials with this BUD to 5 patients.

07/30/2018 – ACRX dispensed vials with this BUD to 3 patients.

08/02/2018 – ACRX dispensed vials with this BUD to 1 patient.

17.

The BUD dates on every vial from Lot No. 06072018@12 should have been the same. Each BUD should have been three days after ACRX compounded the product on June 7, 2018.

18.

ACRX's compounding worksheet for Lot No. 06072018@12 indicates that:

> According to USP guidelines, in the absence of passing a sterility test the storage periods for compounded sterile preparations (high risk) cannot exceed the following time periods.
>
> Controlled Room Temp - - - - not more than 24 hours
>
> Cold temperature- - - - - - - - not more than 3 days

19.

Igbinovia compounded the batch designated as Lot No. 06072018@12. He did not assign a three-day BUD to any of the vials of HCG from that batch.

20.

Igbinovia performed the final product verification on Prescription No. 400989 prior to dispensing the two vials of HCG to C.B. He failed to detect that the product was already expired—beyond the BUD—and he approved both vials for dispensing.

21.

Igbinovia was the pharmacist who sold Prescription No. 400989 to patient C.B. on behalf of ACRX.

22.

Prescription No. 400989 was a new prescription for C.B. Igbinovia did not provide counselling to C.B. for that medication when he dispensed it.

23.

After C.B. returned home with the two vials of HCG from ACRX, she injected a dose, then discovered that both vials were expired. ACRX allowed her to return both vials and it replaced them with vials of medication with a BUD of October 7, 2018.

24.

The replacement vials of HCG that ACRX provided to C.B. came from a batch that Igbinovia compounded and designated as Lot No. 08232018@11.

25.

Igbinovia compounded Lot No. 08232018@11 on August 23, 2018 and assigned a 45-day BUD of October 7, 2018 to the replacement vials of HCG that ACRX dispensed to C.B..

26.

Respondents should have assigned a three-day BUD to each of the vials from Lot No. 08232018@11 because they did not have documentation of stability and sterility testing to support an extended BUD of more than three days.

27.

At the time ACRX dispensed the replacement vials of HCG to C.B., Respondents had not conducted stability or sterility testing on the HCG product that ACRX dispensed to C.B. They did not have documentation to support the 45-day BUD they assigned to the two replacement vials of HCG that ACRX dispensed to C.B. from Lot No. 08232018@11.

28.

Prescription No. 400989 was a verbal prescription called in by C.B.'s physician to ACRX. Igbinovia took the call and recorded the information for Prescription No. 400989. He did not record the ICD 10 code(s) or the days' supply for that prescription.

29.

HCG was commercially available at the time ACRX compounded Lot Nos. 06072018@12 and 08232018@11.

30.

HCG was commercially available when Respondents compounded and dispensed it to C.B.

31.

Respondents did not have, nor could they document, a significant medical reason for compounding HCG for patient C.B. in June and August 2018, when that product was commercially available.

32.

Respondents had no significant medical reason for compounding HCG for their customers in June and August 2018 when HCG was commercially available.

33.

Respondents should have filled Prescription No. 400989 using commercially available product.

34.

Igbinovia did not understand during the Board's investigation that compounded HCG for injection constitutes high-risk compounding. When asked "[w]hat is the risk level in compounding the HCG?", Igbinovia responded "none".

35.

ACRX is open for business weekly, Mondays through Fridays. Upon request, Igbinovia provided a Board Investigator a daily employee sign-in log for the dates August 17, 2018, through September 21, 2018. No pharmacist signed in on the log or recorded hours on any of the days included on the log and the pharmacy technician hours recorded on the log not complete.

October 2018 Annual Inspection of ACRX

36.

In October 2018, Board Inspectors conducted an annual inspection of ACRX.

37.

During the inspection, Board Inspectors found that Igbinovia and ACRX's staff lack sufficient knowledge and understanding of sterile compounding standards. They observed a general failure by Respondents and their staff to comply with Nevada law and USP 797 guidelines for sterile compounding.

38.

During the inspection, Board Inspectors again found that Respondents assigned extended BUDs—BUDs that were outside of Nevada law and the USP 797 guidelines—on many of its sterile compounded products.

39.

Respondents did not provide documentation to support using extended BUDs on its compounded products in response to the Board Investigators' requests.

40.

ACRX had products on site that were labelled with BUDs that were not consistent with records that Respondents provided to the Board Inspectors for those products for use during the inspection.

41.

Respondents did not maintain their records in a readily retrievable manner and could not provide records or documentation to support the extended BUDs they assigned to the products the Board Inspectors found during the inspection or to explain the inconsistencies between the BUDs recorded on ACRX's products and the BUDs recorded in ACRX's records.

42.

On October 18, 2018, the day after ACRX's annual inspection, a Board Inspector contacted Igbinovia by email to request the documentation Respondents could not provide during the inspection.

43.

The Board Inspector allowed Respondents up to ten days from the October 18, 2018 email to provide the documentation he requested.

44.

The Board Inspector's October 18, 2018 email identified three examples from the products listed on the ACRX spreadsheet it provided for use during the inspection and requested that Respondents "review the attached report and provide [the Board Inspector] with the updated BUD's along with back-up documentation for any product that has a longer BUD than originally reported."

45.

In the same October 18, 2018 email, the Board Inspector identified 13 additional ACRX products that were not listed on the spreadsheet. The Inspector requested that Igbinovia and ACRX "forward your [ACRX's] established BUD, Storage, Risk level and back up documentation for each product so that our report will be complete for all products compounded at your facility [ACRX]."

46.

Neither ACRX nor Igbinovia responded to the Board Inspector's requests.

December 2018 Re-Inspection of ACRX

47.

On December 18, 2018, Board Inspectors conducted an unannounced follow-up inspection of ACRX with the objective of reviewing ACRX's BUDs for the sterile products it compounded.

48.

The Inspector again found that ACRX was compounding high risk medication for patient and "office-use" utilizing BUDs in excess of 797 guidelines.

49.

ACRX still had not conducted sterility or potency testing to support the extended BUDs it assigned to its products.

50.

During the December 18, 2018 inspection, the Board Inspectors found 27 of the 34 sterile products they inspected (79.41%) to be mislabeled, meaning ACRX had no documentation to support the BUD ACRX printed on the label or the documentation ACRX had was insufficient to support the BUD ACRX assigned for each product.

51.

The Board Inspectors quarantined 27 products from ACRX's inventory that did not have testing and/or documentation to support the extended BUD assigned to them.

52.

On December 19, 2018, a Board Inspector emailed ACRX and Igbinovia summarizing the Inspectors' findings from the December 18, 2018 inspection.

53.

On December 27, 2018, Igbinovia responded to the Board Inspector's email and provided an update as to only 14 of the 27 quarantined products.

54.

Neither Igbinovia nor ACRX resolved to the Inspector's request regarding the remaining 13 products quarantined during the December 18, 2018 inspection.

55.

On December 19, 2018, Igbinovia notified the Board Inspector that he intended to remove two of the 27 quarantined products and dispense them to a patient.

56.

One of the two products Igbinovia intended to remove from quarantine was hydroxycobalamin 25mg/ml vials, which respondents labelled with a BUD of 180 days.

Igbinovia and ACRX did not have a potency study to validate a BUD of 180 days for that product.

57.

The other product Igbinovia intended to remove from quarantine was magnesium chloride 20%, which Igbinovia and ACRX stored at room temperature. The potency and sterility testing Respondents had for that product were performed on product that was refrigerated.

58.

By attempting to dispense two quarantined products without proper documentation and without proper potency and sterility testing to support the extended BUD they assigned to their products, Igbinovia and ACRX demonstrated an inadequate knowledge and understanding of sterile compounding standards, or a disregard for those standards and compliance with the applicable law.

59.

In the inspection forms from the Board's 2018 inspections of ACRX, the Board Inspectors made approximately 30 notations for which they requested responses within specific deadlines. A summary of those annotations, the response deadlines the Inspector gave to Respondents and Respondents' responses are as follows:

1. Extended BUDs were put on sterile compounded products without any documentation to support the dates used. The Inspector requested a response within 10 days. Igbinovia and ACRX responded for the first time on December 27, 2018, two months after the request and weeks after the Board's reinspection of ACRX on December 18, 2018.

2. "Please complete Retail Inspection Form & send to NVBOP within 3 business days." Respondents responded for the first time on December 22, 2018, two months after the request.

3. "Reviewed Media fill testing for PIC. Date of the last media fill test was 07/30/18. PIC unable to produce any prior testing. Please send last 2 years of testing to NVBOP within 10 business days." Respondents never responded.

4. "Reviewed glove fingertip testing results. Date of the last test was identified as 7/30. It is unknown in what year the test took place. Please list year of test on any form requiring a date. Recommend adding what constitutes pass/fail on form (i.e. >3 cfu would be failure). PIC unable to produce any prior testing. Please send last 2 years of testing to NVBOP within 10 days." Respondents never responded.

5. "PIC will complete training of all compounding personnel and provide documentation of training to BOP by 10/31/2018." Respondents responded for the first time on December 22, 2018, nearly two months after the request.

6. On October 17, 2018, the Board Inspectors provided Respondents a summary of notes they documented during the annual inspection on October 17, 2018. They provided that summary to Respondents on October 18, 2018, with the request "Please forward the information to us within 10 business days." As of December 18, 2018, the date of ACRX's unannounced re-inspection, Respondents had not responded.

60.

As of the date of this Accusation, neither Igbinovia nor ACRX fully responded to the Board Inspectors' requests and safety concerns identified during ACRX's October 18, 2018 inspection and/or its December 18, 2018 re-inspection.

FDA INSPECTION

61.

On February 25, 2018, the Federal Drug Administration (FDA) began an inspection of ACRX. That inspection concluded on March 20, 2018.

62.

A summary of the FDA Inspector's observations includes:

> **Observation #1** – Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.
>
> **Observation #2** – Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Observation #3 – There is not a written testing program designed to assess the stability characteristics of drug products.

Observation #4 – The distribution system is deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Observation #5 – Written procedures for cleaning and maintenance fail to include maintenance and cleaning schedules, description in sufficient detail of methods, equipment and materials used, description in sufficient detail of the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance, instructions for protection of clean equipment from contamination prior to use and parameters relevant to the operation.

Observation #6 – Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Observation #7 – Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Observation #8 – Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Observation #9 – Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

63.

During the FDA inspection, an FDA Inspector asked Igbinovia if ACRX was shipping prescription drugs out of Nevada. Igbinovia denied shipping products out of Nevada.

64.

Igbinovia later admitted his answer to the FDA Inspector's question was false. ACRX was shipping medication to Arizona doctors' offices and billing those offices directly.

65.

ACRX does not have an FDA 503(B) license authorizing it to ship bulk compounded sterile products to entities rather than end users.

66.

Igbinovia told the FDA Inspector on February 28, 2019, that Respondents would cease shipping and billing medication to doctors' offices immediately. ACRX did not stop until a month later, on April 8, 2019, when it notified its customers that it would no longer sell to doctors' offices.

67.

Board Inspectors requested a copy of Respondents' April 8, 2019 notice to its customers. Neither Igbinovia nor ACRX responded.

68.

ACRX responded to the FDA's nine observations on or about April 5, 2019. That matter remains open.

DEA Allegations

In September 2018, the Drug Enforcement Administration (DEA) determined that ACRX was delivering patient-specific prescriptions to clinics for dispensing.

69.

DEA detected that Respondents continued to ship patient-specific prescriptions to clinics during two subsequent visits to ACRX and warned Respondents to cease that practice.

70.

In September 2018, the DEA charged ACRX for delivering/shipping patient-specific prescriptions to clinics and doctors' offices.

71.

ACRX billed at least 113 patient-specific prescriptions to clinics.

72.

The medications associated with those prescriptions were picked up at ACRX, delivered to the patients' homes or were delivered to the clinic to which the prescription was billed.

FIRST CAUSE OF ACTION
Storing and Dispensing Expired Medications

73.

"A drug may not be dispensed or distributed after the expiration date of the drug." NAC 639.473(2); *see also* NRS 585.520 (prohibiting the sale of misbranded drugs). "Outdated drugs must be removed from stock and identified and maintained separately from other stock until disposal." NAC 639.473(3), *see also* NAC 639.050(2) ("Each practitioner or pharmacy shall physically separate each controlled substance which is outdated, damaged, deteriorated, misbranded or adulterated from the balance of its stock medications.") and NAC 639.601(1)("A prescription drug that is outdated, damaged, deteriorated, misbranded or adulterated must be separated from other prescription drugs until it is destroyed or returned to the supplier."). "A drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular." NRS 585.410, *see also* NRS 585.380 and 585.470.

74.

By storing and including in ACRX's inventory prescription drugs that were expired and/or misbranded with BUDs on the label that were false or misleading as to when the drugs would expire and whether the drugs had expired, and by dispensing vials of expired and/or misbranded HCG to patient C.B. on August 23, 2018 and October 7, 2018, and at other times to other patients to whom ACRX dispensed compounded products with incorrect BUDs, Respondents, and each of them, violated NRS 585.520, NAC 639.473(2) and (3), NAC 639.050(2) and/or NAC 639.601(1).

SECOND CAUSE OF ACTION
Dispensing Based on Incomplete Prescription

75.

NAC 453.440 Prescriptions: Contents; additions and changes.

1. Except as otherwise provided in subsection 3, each prescription for a controlled substance must contain:

. . . .

(h) *The days' supply of the controlled substance;*

(i) *The ICD-10 code that corresponds to the diagnosis for which the controlled substance is prescribed*;

(j) The classification of the license of the prescribing practitioner . . . .

NAC 453.440(1)(*emphasis added*).

76.

By filling Prescription No. 400989 without the ICD-10 code(s) and without the days' supply recorded on the prescription form, Respondents, and each of them, violated NAC 453.440(1).

THIRD CAUSE OF ACTION
Compounding Commercially Available Controlled Substances

77.

Nevada pharmacists are prohibited from compounding products that are commercially available. *See* 21 U.S.C. 503A(b)(1)(D) ("A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician -- (D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.") "[T]he term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product." 21 U.S.C. 503A(b)(2).

78.

By compounding HCG products that were commercially available at the time, including the batches of HCG designated as Lot Nos. 06072018@12 and 08232018@11 from which ACRX dispensed vials to C.B., Igbinovia and ACRX violated 21 U.S.C. 503A(b)(1)(D). For those violations, Respondents, and each of them, are subject to discipline pursuant to NRS 639.210(11).

FOURTH CAUSE OF ACTION

Dispensing Medications with Unsupported Extended Beyond Use Dating
(Prescription No. 400989)

79.

NAC 639.67067 High-risk sterile compounding: Process and storage.

1. A compounded drug product is a high-risk sterile compounded drug product if:

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is contaminated with or at a high risk of becoming contaminated with infectious microorganisms; and

(c) One or more of the following conditions are present:

(1) One or more of the ingredients or devices used in the compounding process are nonsterile; or

(2) One or more of the ingredients or devices used in the compounding process were sterile but were exposed or are suspected of having been exposed for more than 1 hour to an air quality inferior to an ISO Class 5 environment.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a high-risk sterile compounded product must not exceed:

(a) Twenty-four hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Three days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

80.

By assigning a BUD of 45 days from the date of compounding to its high-risk sterile compounded products, including the HCG products included in Lot Nos. 06072018@12 and 08232018@11, without testing for sterility and potency to support a 45-day BUD for those products, Respondents, and each of them, violated NAC 639.67067(2).

FIFTH CAUSE OF ACTION

Dispensing Medications with Unsupported Extended Beyond Use Dating

(Products Discovered During December 2018 Re-Inspection)

81.

NAC 639.67067 High-risk sterile compounding: Process and storage.

1. A compounded drug product is a high-risk sterile compounded drug product if:

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is contaminated with or at a high risk of becoming contaminated with infectious microorganisms; and

(c) One or more of the following conditions are present:

(1) One or more of the ingredients or devices used in the compounding process are nonsterile; or

(2) One or more of the ingredients or devices used in the compounding process were sterile but were exposed or are suspected of having been exposed for more than 1 hour to an air quality inferior to an ISO Class 5 environment.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a high-risk sterile compounded product must not exceed:

(a) Twenty-four hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Three days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

82.

By assigning a BUD of 45 days from the date of compounding to its high-risk sterile compounded products, including the 27 products the Board Inspector discovered in ACRX's inventory and quarantined during the December 18, 2018 re-inspection of ACRX, Respondents, and each of them, violated NAC 639.67067(2).

SIXTH CAUSE OF ACTION
Failure to Conduct Required Testing

83.

NAC 639.67071 High-risk sterile compounding: Testing of certain drug products.

1. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for injection into the vascular system or central nervous system shall test a quantity of the high-risk sterile compounded drug product for:

(a) Sterility using a membrane filtration method or an equivalent method, as determined by the Board, before any of the compounded drug product may be administered or dispensed to a patient; and

(b) Excessive bacterial endotoxins using an appropriate test, as determined by the Board, for the particular product at issue before any of the compounded drug product may be administered or dispensed to a patient.

2. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for inhalation or ophthalmic use shall test a quantity of each such high-risk sterile compounded drug product for sterility.

3. The provisions of subsections 1 and 2 apply only to high-risk sterile compounded drug products:

(a) Compounded in groups of more than 25 identical individual single-dose packages;

(b) Compounded in multiple-dose vials for administration to multiple patients; or

(c) That will be exposed for a period of more than:

(1) Twelve hours to temperatures of at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(2) Six hours to temperatures exceeding 8 degrees Celsius (46 degrees Fahrenheit) before the compounded drug product is sterilized.

4. If any high-risk sterile compounded drug product tested pursuant to this section tests positive for antimicrobial growth or endotoxin production, the high-risk sterile compounded drug product must not be administered or dispensed to a patient.

84.

By failing to conduct batch testing of the high-risk sterile compounded drug products it compounded and dispensed as required by NAC 639.67071 and as alleged in the factual allegations above, Respondents, and each of them, violated NAC 639.67071.

SEVENTH CAUSE OF ACTION
Staff Working Outside Scope of Training

85.

NAC 639.67013 Competency and proficiency of certain pharmaceutical personnel.

1. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall ensure that each pharmacist and pharmaceutical technician engaged in the practice of compounding drug products:

(a) Is competent and proficient in compounding the drug products that the pharmacist or pharmaceutical technician will be authorized and expected to compound;

(b) Complies with the provisions of NAC 639.661 to 639.690, inclusive, concerning the drug products which the pharmacist or pharmaceutical technician compounds and the compounded drug products which the pharmacist or pharmaceutical technician dispenses at the pharmacy; and

(c) Receives, on an ongoing basis, sufficient training to maintain that competency and proficiency.

2. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall evaluate the competency and proficiency of a pharmacist and pharmaceutical technician:

(a) If the pharmacist or pharmaceutical technician is newly hired or is newly assigned to compound drug products, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound drug products; and

(b) If the pharmacist or pharmaceutical technician will be assigned to compound drug products that involve a higher level of risk than the drug products which the pharmacist or pharmaceutical

technician had previously been trained to compound, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound those drug products.

86.

By engaging in the practice of compounding and allowing inadequately trained pharmacy staff, including Igbinovia, to compound sterile drug products, Respondents, and each of them, violated NAC 639.67013 and/or engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i).

EIGHTH CAUSE OF ACTION
Failure to Adequately Counsel

87.

NRS 639.266 requires a pharmacist, on receipt of a prescription and after review of the patient's record, to communicate with the patient, or a person caring for the patient, matters that will enhance the patient's therapy through drugs. NAC 639.707(1) and (2) require that discussion to include, among other things, the name of the drug, dosage and administration instructions, the intended use of the drug, common side effects, and other information that is necessary for the safe and effective use of the drug. A pharmacist who performs those duties in an "incompetent, unskillful or negligent manner" is guilty of unprofessional conduct pursuant to NAC 639.945(1)(i).

88.

Respondents Igbinovia and ACRX violated NRS 639.266, NAC 639.707(1) and (2) and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i) by failing to counsel C.B. as to Prescription No. 400989.

[THIS AREA INTENTIALLY LEFT BLANK]

NINTH CAUSE OF ACTION
Failure to Keep Daily Employee Records

89.

> NAC 639.245 Maintenance and availability of records regarding certain pharmaceutical personnel on duty; activities of pharmaceutical technicians.
>
> 1. 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. This record must be:
>
> (a) Readily retrievable; and
>
> (b) Retained for 2 years.

90.

By failing to maintain and provide an accurate copy of ACRX's employee sign-in log, including failing to keep of complete log of pharmacist(s) and technician(s) who worked each day, as alleged herein, and by failing to maintain accurate records as alleged in paragraph 35 above, Respondents, and each of them, violated NAC 639.245(1).

TENTH CAUSE OF ACTION
Failure to Maintain and Produce Prescription Records Upon Request

91.

Prescription records must be readily retrievable and maintained and produced in conformance with NRS 454.286, NAC 639.482, NAC 639.485(1), NAC 639.910(1) and NAC 639.935. Those records must be made available and produced to any Board Inspector or Board Investigator upon request. NRS 454.291(2), NAC 639.914(1)(b) and NAC 639.935(4)(b).

92.

By failing to maintain and timely produce records to Board Investigators and/or Board Inspectors upon request, Respondents, and each of them, violated NRS 454.286; NRS 454.291(2), NAC 639.910(1), NAC 639.914(1)(b) and/or NAC 639.935.

ELEVENTH CAUSE OF ACTION
Billing and Dispensing Compounded Medications to Non-End users

93.

"A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients." 21 C.F.R. § 1306.04(b). The term "dispense" means to be delivered to an ultimate user, which is defined as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use and for the use of a member of his household . . . ." 21 U.S.C. § 802(10), 21 U.S.C. § 802(27).

94.

By dispensing prescriptions that were billed to a clinic and then dispensed to a clinic instead of the end user (patient), Respondents, and each of them, violated federal law, particularly 21 C.F.R. § 1306.04(b), which is grounds for discipline against them pursuant to NRS 639.210(11).

TWELVETH CAUSE OF ACTION
Unprofessional Conduct

95.

> 1. The following acts or practices by a holder of any license, certificate or registration issued by the Board . . . are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest:
>
> (a) Manufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations.
>
> . . . .
>
> (i) Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner . . . . [and]
>
> . . . .
>
> (m) Failing to provide any document, data or information that is required to be made and maintained pursuant to chapters 453, 454, 858 and 639 of NRS and chapters 453, 454, 585 and 639 of

> NAC to a member of the Board or a member of the staff of the Board upon his or her request.
> 2. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ.

NAC 639.945(1)(a), (i) and (m), and (2).

96.

By engaging in the conduct alleged herein, including in paragraphs 2 through 72 and each of the Causes of Action herein, Igbinovia and/or ACRX, engaged in unprofessional conduct and conduct contrary to the public interest. Unprofessional conduct or conduct that is contrary to the public interest, including conduct as defined by NAC 639.945(1)(a), (i) and (m) and part (2), are grounds for the suspension or revocation of any certificate, license, registration or permit issued pursuant to NRS Chapter 639. NRS 639.210(4).

THIRTEENTH CAUSE OF ACTION
Managing Pharmacist Responsibilities

97.

As the managing pharmacist/pharmacist in charge of ACRX at the time of each of the violations alleged herein, Respondent Igbinovia is responsible for those violations, including those of his employees. *See* NRS 639.0087, NRS 639.210(15), NRS 639.220(3)(c), NRS 639.230(5), NAC 639.510(2) and NAC 639.702.

FOURTEENTH CAUSE OF ACTION
Pharmacy/Pharmacy Owner Responsibility

98.

NAC 639.945(2) states that "[t]he owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ". At the time of the violations alleged herein, Igbinovia was the owner of ACRX. As such, he is responsible for the violations, the unprofessional conduct and the conduct that was contrary to the public interest as defined in NAC 639.945.

99.

For the violations and conduct alleged in each of the factual allegations and Causes of Action stated above, Respondent EGHOMWARE IGBINOVIA, Certificate of Registration No. 16316, and Respondent ACRX SPECIALTY PHARMACY, Certificate of Registration No. PH03673, are each subject to discipline pursuant to NRS 453.236, NRS 453.241(1) and (3), NRS 639.210(4), (9), (11), (12), (15) and/or (17), NRS 639.230(5), NRS 639.255, NAC 639.900 and/or NRS 639.255.

100.

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 25th day of July 2019.

J. David Wuest, R.Ph., 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. NRS 233B.127(3). 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. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. To do so, you must mail to the Board within twenty (20) 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,	)	**CASE NOS. 18-082-RPH-S**
	)	**18-082-PH-S**
Petitioner,	)	**18-131-RPH-S**
v.	)	**18-131-PH-S**
	)	
EGHOMWARE IGBINOVIA (AKA JERRY IGBINOVIA), Certificate of Registration No. 16316, and	)	**STATEMENT TO THE RESPONDENT NOTICE OF INTENDED ACTION AND ACCUSATION RIGHT TO HEARING**
ACRX SPECIALTY PHARMACY, Certificate of Registration No. PH03673,	)	
Respondents.	)	

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 and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, 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 show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). 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. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 4, 2019, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of July, 2019.

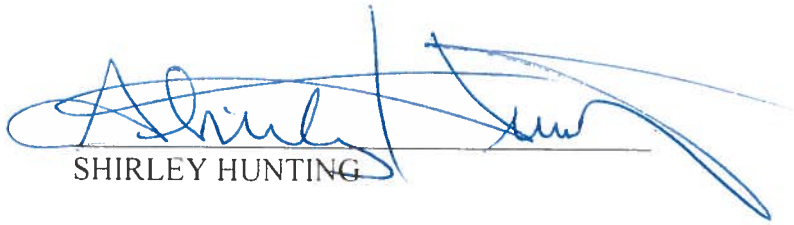
J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of July. 2019. I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

EGHOMWARE IGBINOVIA (AKA JERRY IGBINOVIA)
7568 Mossback St.
Las Vegas, NV 89123

ACRX Specialty Pharmacy
3204 Soaring Gulls #101
Las Vegas, NV 89118



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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **V.** **EGHOMWARE IGBINOVIA (AKA JERRY IGBINOVIA), Certificate of Registration No. 16316, and** **ACRX SPECIALTY PHARMACY, Certificate of Registration No. PH 03673** **Respondent.**	**OBJECTION, STATEMENT OF COMPLIANCE, ANSWER, AND NOTICE OF DEFENSE** **CASE NOS. 18-082-RPH-S** **18-082-PH-S** **18-131-RPH-S** **18-131-PH-S** **(Consolidated Cases)**

COMES NOW Eghomware Igbinovia (aka Jerry Igbinovia, herein ("Igbinovia")), Certificate of Registration No. 16316, and ACRX Specialty Pharmacy, Inc., Certificate of Registration No. 03673, (herein "ACRX" or collectively, "Respondents") by and through their counsel Holland & Hart LLP, and submits their objection, statement of compliance, and answer to the Nevada State Board of Pharmacy's ("Board['s]") Notice of Intended Action and Accusation ("Accusation").

OBJECTION

Pursuant to NRS 639.244(1)(a) and NRS 233B.121(4), Respondents object to the Board's Accusation to the extent that its contents are based on facts and circumstances currently pending in the action styled as *ACRX Specialty Pharmacy, Inc. et al. v. Nevada State Board of Pharmacy*, Case No. A-19-798928-C, pending before Department II of the Eighth Judicial District Court for Clark County, Nevada and filed on July 22, 2019 ("the District Court Case"). The Court has already made a number of its own findings in the District Court Case regarding the Board's allegations against Respondents, and conduct described within the Accusation.

The District Court Case predates the Accusation and the Board's retention of jurisdiction over facts and allegations addressed by the District Court subverts the principles of due process and *res judicata*. *See Britton v. City of N. Las Vegas*, 106 Nev. 690, 692, 799 P.2d 568, 569 (1990) (holding that res judicata principles also apply in administrative proceedings). To the extent there is any overlap between the subject matter, facts, and allegations at issue in this proceeding and the District Court Case, the Board should relinquish jurisdiction over the Accusation. Otherwise, the District Court and the Board potentially are subject to multiple, inconsistent rulings. Respondents' Complaint, *Ex Parte* Motion for Temporary Restraining Order and Preliminary Injunction, and the District Court's Temporary Restraining Order, are attached hereto as **Exhibits A-C**.

STATEMENT OF COMPLIANCE

The allegations in this Accusation stem from Board inspections occurring in October and December of 2018. The majority of the allegations in the Accusation are also items identified by the the federal Food and Drug Administration ("FDA") after it conducted an observation of Respondents in March of 2019. In April of 2019, Respondents issued a response to the FDA's observations detailing their remedial efforts, including certification of Igbinovia's further training in sterile compounding. At the end of the FDA's observation of Respondents, the FDA took no adverse action with respect to the Respondents, their business operation, or any of their lawfully compounded pharmaceuticals.

ACRX holds a valid DEA registration and, thus, is subject to the jurisdiction of the DEA. The DEA, which possesses broad powers to suspend and revoke DEA registrations, also

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investigated Plaintiffs and their pharmacy operations. When the DEA finds that there is "imminent danger to the public health or safety," it may suspend a person's registration and order him or her to show cause why the license should not be revoked or suspended. 21 C.F.R. § 1301.36(e). The DEA, however, never instituted any suspension or revocation proceedings regarding the Respondents.

The majority of the allegations in the Accusation are premised upon Respondents' use of Beyond Use Dates ("BUD") exceeding recommended timeframes if certain testing is performed. As stated in Respondents response to the FDA, attached hereto as **Exhibit D**, ACRX has performed potency testing every 30-60 days over the course of the shelf-life of the product in order to establish the BUD. Documentation of all potency testing was provided to the Investigator. In addition, ACRX has also tested all stock solutions for sterility and for potency over the course of the shelf-life of the product, and all stock solutions contain an anti-microbial preservative.

Moreover, since the inspection giving rise to the Accusation, Respondents have re-trained their staff, updated standard operating procedures, remedied software deficiencies, implemented robust logging and record keeping procedures, updated sterilization equipment and processes, and completed an observational competency assessment and onsite training session conducted by Dr. Ross Caputo, CEO and President of Eagle Analytical Services, Inc., at ACRX. Accordingly, Respondents have demonstrated that Respondents are in compliance with all lawful requirements regarding their respective certificates of registration.

ANSWER

Pursuant to NRS 639.244(1)(b) and NRS 233B.121(4), Respondents hereby answer and respond to the allegations in the Accusation as follows:

JURISDICTION

1. Answering paragraph 1 of the Accusation, this paragraph calls for a legal conclusion to which no admission or denial is required; nonetheless, Respondents deny the allegations contained in this paragraph.

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FACTUAL ALLEGATIONS

2. Answering paragraph 2 of the Accusation, Respondents admit only that Igbinovia "owned" ACRX, but cannot fairly admit or deny whether Igbinovia "operated" ACRX due to the vagueness of the term and otherwise deny the allegations of this paragraph.

3. Answering paragraph 3 of the Accusation, Respondents admit only Igbinovia was ACRX's managing pharmacist and otherwise deny the allegations within this paragraph.

4. Answering paragraph 4 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

5. Answering paragraph 5 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

6. Answering paragraph 6 of the Accusation, Respondents deny the allegations in this paragraph.

7. Answering paragraph 7 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

8. Answering paragraph 8 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

9. Answering paragraph 9 of the Accusation, the document referenced speaks for itself, and no response is required of Respondents; nonetheless, to the extent an answer is required to the allegations within this paragraph, Respondents deny them.

10. Answering paragraph 10 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, denies the allegations in this paragraph.

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11. Answering paragraph 11 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

12. Answering paragraph 12 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

13. Answering paragraph 13 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

14. Answering paragraph 14 of the Accusation, Respondents deny the allegations in this paragraph.

15. Answering paragraph 15 of the Accusation, the documents referenced speak for themselves, and no response is required of Respondents; nonetheless, to the extent an answer is required to the allegations within this paragraph, Respondents deny them.

16. Answering paragraph 16 of the Accusation, the documents referenced speak for themselves, and no response is required of Respondents; nonetheless, to the extent an answer is required to the allegations within this paragraph, Respondents deny them.

17. Answering paragraph 17 of the Accusation, Respondents deny the allegations in this paragraph.

18. Answering paragraph 18 of the Accusation, the documents referenced speak for themselves, and no response is required of Respondents; nonetheless, to the extent an answer is required to the allegations within this paragraph, Respondents deny them.

19. Answering paragraph 19 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

20. Answering paragraph 20 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

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21. Answering paragraph 21 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

22. Answering paragraph 22 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph, and further cannot fairly respond to the vague and ambiguous use of "counselling" as used within this paragraph, and on these bases deniy the allegations in this paragraph.

23. Answering paragraph 23 of the Accusation, Respondents deny the allegations in this paragraph.

24. Answering paragraph 24 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

25. Answering paragraph 25 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

26. Answering paragraph 26 of the Accusation, this paragraph calls for a legal conclusion to which no admission or denial is required; nonetheless, Respondents deny the allegations contained in this paragraph.

27. Answering paragraph 27 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph, and cannot fairly respond to this paragraph's vague and ambiguous use of "documentation"; on these bases, deny the allegations in this paragraph.

28. Answering paragraph 28 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

29. Answering paragraph 29 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

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30. Answering paragraph 30 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph, and cannot adequately respond in the format of this Response to the Accusation about the conclusory allegation that HCG was "commercially available," which ultimately is a legal conclusion based on FDA regulations; on these bases, Respondents deny the allegations in this paragraph.

31. Answering paragraph 31 of the Accusation, Respondents deny the allegations in this paragraph.

32. Answering paragraph 32 of the Accusation, Respondents deny the allegations in this paragraph.

33. Answering paragraph 33 of the Accusation, Respondents deny the allegations in this paragraph.

34. Answering paragraph 34 of the Accusation, Respondents deny the allegations in this paragraph.

35. Answering paragraph 35 of the Accusation, Respondents admit ACRX is open for business weekly Mondays through Fridays; as to the remainder of the paragraph the documents referenced speak for themselves and no admission or denial is required of Respondents. To the extent an admission or denial is required, Respondents deny the allegations in the remainder of the paragraph.

36. Answering paragraph 36 of the Accusation, Respondents admit the allegations in this paragraph.

37. Answering paragraph 37 of the Accusation, the allegations of which are directed to third parties other than Respondents and seek admissions or denials as to the findings and observations of third parties, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

38. Answering paragraph 38 of the Accusation, the allegations of which are directed to third parties other than Respondents and seek admissions or denials as to the findings and

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observations of third parties, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

39. Answering paragraph 39 of the Accusation, Respondents deny the allegations in this paragraph.

40. Answering paragraph 40 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the vague, unspecified allegations about "products" within the pharmacy contained in this paragraph and, on that basis, deny the allegations in this paragraph.

41. Answering paragraph 41 of the Accusation, Respondents deny the allegations in this paragraph.

42. Answering paragraph 42 of the Accusation, Respondents admit only that they received an email from the Board inspector on October 18, 2018 requesting documentation, and otherwise deny the remainder of the allegations in this paragraph.

43. Answering paragraph 43 of the Accusation, the document referenced speaks for itself, and no response is required of Respondents. To the extent any admission or denial is required, Respondents deny the allegations in this paragraph.

44. Answering paragraph 44 of the Accusation, the document referenced speaks for itself, and no response is required of Respondents. To the extent any admission or denial is required, Respondents deny the allegations in this paragraph.

45. Answering paragraph 45 the document referenced speaks for itself, and no response is required of Respondents. To the extent any admission or denial is required, Respondents deny the allegations in this paragraph.

46. Answering paragraph 46 of the Accusation, Respondents deny the allegations in this paragraph.

47. Answering paragraph 47 of the Accusation, Respondents admit only that the Board conducted an inspection of ACRX on December 18, 2018; otherwise, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the

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remainder of this paragraph and, on that basis, deny each and every unadmitted allegation within this paragraph.

48. Answering paragraph 48 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

49. Answering paragraph 49 of the Accusation, Respondents deny the allegations in this paragraph.

50. Answering paragraph 50 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

51. Answering paragraph 51 of the Accusation, Respondents admit only that the Board quarantined products from ACRX's inventory, deny the exact quantity quarantined by the Board pending further investigation and review by Respondents, and otherwise deny the remainder of the unadmitted allegations in this paragraph.

52. Answering paragraph 52 of the Accusation, Respondents admit only that the Board emailed ACRX on December 19, 2018. The remainder of the paragraph the document referenced speaks for itself, and does not require any admission or denial from Respondents. To the extent any admission or denial is required, Respondents deny the unadmitted allegations in this paragraph.

53. Answering paragraph 53 of the Accusation, Respondents admit only that the Igbinovia emailed the Board on December 27, 2018. The remainder of the paragraph the document referenced speaks for itself, and does not require any admission or denial from Respondents. To the extent any admission or denial is required, Respondents deny the unadmitted allegations in this paragraph.

54. Answering paragraph 54 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

55. Answering paragraph 55 of the Accusation, Respondents deny the allegations in this paragraph.

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56. Answering paragraph 56 of the Accusation, Respondents deny the allegations in this paragraph.

57. Answering paragraph 57 of the Accusation, Respondents deny the allegations in this paragraph.

58. Answering paragraph 58 of the Accusation, Respondents deny the allegations in this paragraph.

59. Answering paragraph 59 of the Accusation, to the extent the paragraph references documents, the documents referenced speak for themselves, and no admission or denial is required of Respondents; to the extent this paragraph requires an admission or denial from Respondents, they deny the allegations relating to such documents. As to the remainder of pragraph 59, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

60. Answering paragraph 60 of the Accusation, Respondents deny the allegations in this paragraph.

61. Answering paragraph 61 of the Accusation, Respondents admit the allegations in this paragraph.

62. Answering paragraph 62 of the Accusation, to the extent the paragraph references a document, the document referenced speaks for itself, and no admission or denial is required of Respondents; to the extent this paragraph requires an admission or denial from Respondents, they deny the allegations relating to such documents. As to the remainder of paragraph 62, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph..

63. Answering paragraph 63 of the Accusation, Respondents deny the allegations in this paragraph.

64. Answering paragraph 64 of the Accusation, Respondents deny the allegations in this paragraph.

65. Answering paragraph 65 of the Accusation, Respondents admit only that ACRX does not possess a license to operate as a 503(B) compounding pharmacy, and otherwise deny all

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other unadmitted allegations within this paragraph, which themselves call for legal conclusions to which no admission or denial is required.

66. Answering paragraph 66 of the Accusation, Respondents deny the allegations in this paragraph.

67. Answering paragraph 67 of the Accusation, Respondents deny the allegations in this paragraph.

68. Answering paragraph LVIII of the Accusation, Respondents admit only that Respondents responded to the FDA's observations on April 5, 2019, and otherwise and deny the unadmitted allegations in this paragraph, as the allegations of this paragraph pertain to the operations of a federal administration beyond Respondents' knowledge or control.

"DEA Allegations" – The Accusation contains an unnumbered paragraph titled "DEA Allegations" on Page 13, located between numbered paragraphs 68 and 69, the allegations of which Respondents deny.

69. Answering paragraph 69 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and its allegations are vague and ambiguous as to time and duration of the alleged conduct. On these bases, Respondents deny the allegations in this paragraph.

70. Answering paragraph 70 of the Accusation, Respondents specifically deny that the DEA "charged" ACRX in September of 2018, and further deny all other allegations within this paragraph.

71. Answering paragraph 71 of the Accusation, the Accusation is vague and ambiguous as to the conduct described as ACRX having "billed" "patient-specific prescriptions to clinics," and cannot fairly meet such accusations with an admission or denial. Further, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph. On these bases, Respondents deny the allegations in this paragraph.

72. Answering paragraph 72 of the Accusation, Respondents lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph and, on that basis, deny the allegations in this paragraph.

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FIRST CAUSE OF ACTION

73. Answering paragraph 73 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

74. Answer paragraph 74 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

SECOND CAUSE OF ACTION

75. Answering paragraph 75 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

76. Answering paragraph 76 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

THIRD CAUSE OF ACTION

77. Answering paragraph 77 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

78. Answering paragraph 78 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

FOURTH CAUSE OF ACTION

79. Answering paragraph 79 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

80. Answering paragraph 80 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

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FIFTH CAUSE OF ACTION

81. Answering paragraph 81 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

82. Answering paragraph 82 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

SIXTH CAUSE OF ACTION

83. Answering paragraph 83 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

84. Answering paragraph 84 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

SEVENTH CAUSE OF ACTION

85. Answering paragraph 85 of the Accusation, this paragraph contains conclusions of law to which no answer is required. The extent an answer is required, Respondents deny the allegations in this paragraph.

86. Answering paragraph 86 of the Accusation, this paragraph contains conclusions of law to which no answer is required. The extent an answer is required, Respondents deny the allegations in this paragraph.

EIGHTH CAUSE OF ACTION

87. Answering paragraph 87 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

88. Answering paragraph 88 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

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NINTH CAUSE OF ACTION

89. Answering paragraph 89 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

90. Answering paragraph 90 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

TENTH CAUSE OF ACTION

91. Answering paragraph 91 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

92. Answering paragraph 92 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

ELEVENTH CAUSE OF ACTION

93. Answering paragraph 93 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

94. Answering paragraph 94 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

TWELVETH CAUSE OF ACTION

95. Answering paragraph 95 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

96. Answering paragraph 96 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.'

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THIRTEENTH CAUSE OF ACTION

97. Answering paragraph 97 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

FOURTEENTH CAUSE OF ACTION

98. Answering paragraph 98 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

99. Answering paragraph 99 of the Accusation, this paragraph contains conclusions of law to which no answer is required. To the extent an answer is required, Respondents deny the allegations in this paragraph.

Answering paragraph 100 of the Accusation, this paragraph does not require a response. Moreover, to the extent the Board seeks any disciplinary action, fine, administrative fees, or other remedy or relief against the Board, Respondents deny such request and seek that it be rejected, and that the Board obtain nothing from Respondents by way of its Accusation.

AFFIRMATIVE DEFENSES

1. The Accusation, in whole or in part, fails to state a claim upon which relief may be granted.

2. The Board has failed to plead with sufficient specificity to provide adequate notice to Respondents of the Board's claims, and therefore should be dismissed.

3. Respondents exercised due care and good faith towards the Board and/or complied with all application statutes, administrative code provisions, and/or lawful orders.

4. Respondents have made no false representations to the Board.

5. The Board has not relied to its detriment on any alleged representations made by Respondents to the Board.

6. The Board consented to the acts or omissions alleged to have been committed by Respondents.

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7. The Board has not alleged any facts to demonstrate any harm or damages resulting from the alleged acts or omissions of Respondents.

8. The Board's claims are barred in equity.

9. The Board's claims are barred by the doctrine of unclean hands.

10. The Board's claims are barred by the doctrines of waiver, laches, ratification, and estoppel.

11. The Board's claims are preempted by applicable federal law, and the Board thus lacks jurisdiction to assert such claims.

12. The Board's claims are estopped and cannot proceed due to the previously filed District Court Case, and the Board must dismiss or stay its proceedings due to considerations of *res judicata*, comity, and the first-to-file doctrine.

13. The circumstances referenced in the Accusation are caused by the actions or omissions of another person or entity over which Respondents have no control.

14. All possible affirmative defenses may not have been alleged herein insofar as sufficient facts were not available after reasonable inquiry upon the filing of Respondents' Answer and insofar as the Accusation is couched in conclusory, vague, and ambiguous terms, and therefore Respondents hereby reserve the right to assert additional affirmative defenses.

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PRAYER FOR RELIEF

WHEREFORE, Respondent respectfully requests the following relief:

1. That the hearing currently set for September 4, 2019 in this case be maintained or, if rescheduled, that the hearing be set with adequate time for Respondent to investigate the claims and secure evidence in its defense;

2. That following the hearing this action be dismissed with prejudice;

3. That the Board award Respondents' attorneys' fees and costs incurred in defense of this action; and

4. For such other and further relief as the Board deems proper.

Dated this 14th day of August 2019.

Constance L. Akridge, Esq.
J. Malcolm DeVoy, Esq.
Brittany L. Walker Esq.
HOLLAND & HART LLP
9555 Hillwood Drive, Second Floor
Las Vegas, Nevada 89134

Attorneys for Respondents

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CERTIFICATE OF SERVICE

I hereby certify that on the 14th day of August, 2019, a true and correct copy of the foregoing **OBJECTION, STATEMENT OF COMPLIANCE, ANSWER, AND NOTICE OF DEFENSE** was served by the following method(s):

☒ Email: by electronically delivering a copy via email to the following e-mail address:

Nevada State Board of Pharmacy
S. Paul Edwards, Esq.
General Counsel
Brett Kandt, Esq.
General Counsel
431 W. Plumb Lane
Reno, Nevada 89509
Tel: (775) 850-1440
Fax: (775) 850-1444
Email: pedwards@pharmacy.nv.gov
bkandt@pharmacy.nv.gov

☒ U.S. Mail: by depositing same in the United States mail, first class postage fully prepaid to the persons and addresses listed below:

Nevada State Board of Pharmacy
S. Paul Edwards, Esq.
General Counsel
Brett Kandt, Esq.
General Counsel
431 W. Plumb Lane
Reno, Nevada 89509
Tel: (775) 850-1440
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Email: pedwards@pharmacy.nv.gov
bkandt@pharmacy.nv.gov

An Employee of Holland & Hart LLP

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EXHIBIT A

Electronically Filed
7/23/2019 8:53 AM
Steven D. Grierson
CLERK OF THE COURT

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Attorneys for Plaintiffs

CASE NO: A-19-798928-C
Department 2

DISTRICT COURT

CLARK COUNTY, NEVADA

ACRX SPECIALTY PHARMACY, INC. a Nevada corporation; and EGHOMWARE IGBINOVIA, a/k/a JERRY IGBINOVIA, an individual,

Plaintiffs,

v.

NEVADA STATE BOARD OF PHARMACY; DOES I-X; and ROE CORPORATIONS XI-XX,

Defendants.

Case No.
Dept. No.

COMPLAINT

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Plaintiffs ACRX Specialty Pharmacy Inc. ("ACRX") and Eghomware Igbinovia, a/k/a Jerry Igbinovia ("Igbinovia"), collectively the "Plaintiffs," by and through their attorneys of the law firm of Holland & Hart LLP, file this Complaint against the Nevada State Board of Pharmacy (the "Board"), alleging as follows:

THE PARTIES

1. Plaintiff ACRX is a corporation created pursuant to the laws of the State of Nevada and is authorized to do business in Clark County, Nevada.

2. Plaintiff Igbinovia is a resident of Clark County, Nevada.

Case Number: A-19-798928-C

3. Defendant Board is an agency of the State of Nevada.

4. Defendants Does I through X and Roe Corporations XI through XX are persons or entities whose acts, activities, misconduct or omissions at all times material hereto make them jointly and severally liable under the claims for relief set forth herein. The true names and capacities of the Doe Defendants and Roe Corporate Defendants are presently unknown, but when ascertained, Plaintiffs request leave of the Court to amend the Complaint to substitute their true names and capacities.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction pursuant to Article VI of the Nevada Constitution, and personal jurisdiction over the Defendants under with NRS 14.065, as this Court's jurisdiction is not inconsistent with the Nevada Constitution or the United States Constitution, and in accordance with NRS 41.031, under which the State of Nevada waives its sovereign immunity.

6. Venue is proper in the Eighth Judicial District Court in accordance NRS 41.031.

GENERAL ALLEGATIONS

7. ACRX is a specialty compounding pharmacy that conducts business in Clark County, and holds all required licenses to operate as such.

8. Igbinovia is a duly licensed pharmacist in the State of Nevada, and the sole owner, officer, and managing pharmacist of ACRX.

9. Plaintiffs are engaged in the business of operating a compounding pharmacy, which is regulated by the Nevada State Board of Pharmacy. Under NRS 639.0053, "compounding" is defined as forming or making up a composite product by combining two or more different ingredients. One of the drugs that Plaintiffs regularly compounded was buprenorphine, a substance that aids individuals in treating and overcoming opioid addiction.

10. For many months, Plaintiffs have been the subject of threatening and harassing conduct by the Board that exceeds its legal authority. In addition to conducting its own investigations that, to date, have not resulted in a single accusation (hereinafter an "Accusation," as defined in NRS 639.241) filed against either of the Plaintiffs, the Board recruited the Food and Drug Administration ("FDA") and the Drug Enforcement Administration ("DEA") to further

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investigate Plaintiffs; neither investigation yielded a closure of ACRX.

11. Since June 20, 2019, when the Board instituted an "involuntary closure" of ACRX, Plaintiffs have been unable to continue their regular business activities despite being legally entitled to do so.

A. The Board's Purported Involuntary Closure of ACRX.

12. On June 20, 2019, the Board purported to effect an involuntary closure of ACRX.

13. In a Notice of Involuntary Closure of Pharmacy dated June 21, 2019 (the "Involuntary Closure Notice"), the Board's Office of the General Counsel cited NAC 639.570 as its sole basis for closing ACRX, and stated that "involuntary closure was necessary after federal law enforcement agents arrested [Igbinovia] and seized ACRX Specialty Pharmacy's computer system on June 20, 2019, rendering the pharmacy unable to operate in conformance with applicable law."

14. The Involuntary Closure Notice did not specify what provisions of "applicable law" applied to Plaintiffs, and did not specify whether and how Plaintiffs had violated any law.

15. Since June 20, 2019, the conditions that the Board identified as "necessary" for ACRX's involuntary closure have abated.

16. On June 20, 2019, Igbinovia was released from custody on his personal recognizance. The United States District Court for the District of Nevada did not impose any restrictions on his ability to operate ACRX, or to otherwise engage in pharmaceutical practice, as conditions of his release.

17. In fact, no department or agency of the United States has obtained any order or taken any action to close ACRX (or prohibit it from operating under the management of any pharmacist other than Igbinovia) or to stop, enjoin, or otherwise prohibit Igbinovia from practicing as a pharmacist or operating ACRX.

18. Specifically, the United States Department of Justice and the Drug Enforcement Administration have not suspended or revoked Plaintiffs' DEA Registration under 21 U.S.C. § 824 or 21 C.F.R. § 1301.36, and have not commenced any proceedings to do so under those authorities, which specifically allow the United States to cease the Plaintiffs' pharmacy operations.

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19. Additionally, Igbinovia retained and has access to a full, complete, and secure backup of all data seized from ACRX on June 20, 2019, and is capable of re-installing this data on a new computer to be used in ACRX's operations.

20. As all the conditions the Board deemed necessary to involuntarily close ACRX under NAC 639.570 had been abated, Plaintiffs sought to re-open their pharmacy and resume business. Nonetheless, the Board refused—and refuses to this day—to re-open ACRX, or to grant Igbinovia access to ACRX for any purpose.

B. The Board's Ad Hoc Rationales for Refusing to Re-Open the Pharmacy.

21. Plaintiffs attempted to engage the board and re-open the pharmacy on the basis that the limited grounds for the Board's involuntary closure of ACRX on June 20, 2019 under NAC 639.570 had ceased to be in effect. The Board, however, refused to allow Plaintiffs to re-open their pharmacy for varied and constantly changing reasons.

22. During telephonic conversations with Plaintiffs' counsel, the Board represented that it would allow ACRX to re-open if it ceased any distribution of controlled substances, as defined under the Controlled Substances Act, 21 U.S.C. § 802(6), and NRS Chapter 453, and turned over any controlled substances in ACRX's possession to the Board.

23. Plaintiffs' counsel and the Board continued to discuss this proposal and its feasibility based on ACRX's business model. Plaintiffs considered this proposal until the Board suddenly changed its position and demanded new conditions and restrictions on ACRX's activities as a condition of re-opening.

24. On or about July 10, 2019, the Board informed Plaintiffs' counsel that if they were to allow ACRX to resume operations, an additional requirement—beyond the cessation and surrender of ACRX's controlled substances—was necessary: Plaintiffs would have to cease all compounding activities as well.

25. Plaintiffs believe and therefore allege that these sudden new conditions sought by the Board, before ever filing an accusation against them, are evidence of the Board's dilatory conduct, and show the Board never intended to allow ACRX to re-open.

26. The Board's rationale for this demand was based upon two complaints the Board

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purported to have received, and which were subject to the Board's investigation. Plaintiffs were not aware of either complaint or investigation prior to the July 10, 2019 telephone call between their counsel and the Board.

27. Upon further inquiry by Plaintiffs' counsel, the Board confirmed that it had not filed an Accusation against either of the Plaintiffs in connection with these complaints. The Board refused to identify any details regarding these complaints, including the alleged conduct at issue and what, if any, public harm was implicated by the undisclosed conduct.

28. As the Board is created by statute and has its powers defined by the legislature, its jurisdiction is limited to oversight of pharmacies and pharmacist licenses, and the Board is further constrained by the due process requirements contained within Chapters 233B and 639 of the Nevada Revised Statutes.

29. The Board has already closed ACRX citing NAC 639.570 as its authority for doing so, despite NAC 639.570 being a regulation which provides the Board no authority to close ACRX, and the Board has maintained its actions based on causes that have been resolved since the Board's involuntary closure of ACRX. The Board's continued closure of ACRX is unauthorized and directly affects ACRX's business, depriving Plaintiffs the use of their respective Board-issued licenses without any opportunity for notice and hearing.

30. Moreover, without any hearing or proper notice, the Board has, through its General Counsel, engaged in apparent negotiations to limit the scope of ACRX's operations if it were to re-open.

31. Like the Board's closure of ACRX itself, such negotiations are unauthorized and appear to be conducted in bad faith, as the Board's conditions for ACRX's re-opening change frequently and are increasingly more restrictive regarding the kind of license conduct in which ACRX may engage once re-opened.

32. Illustrating the Board's arbitrary and capricious conduct, the Board's latest justification for its requirement that Plaintiffs not engage in compounding as a condition of re-opening is the undisclosed content of complaints the Board claims to have received against one or

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both Plaintiffs. Yet, the Board has not filed any formal Accusation against either Plaintiff to which he or it may respond and be heard.

C. The Board's Deficient Attempt to Provide ACRX with Notice of an Opportunity to Defend Itself Against Unspecified Claims.

33. On July 11, 2019, the Board issued ACRX (but not Igbinovia) a Statement to the Respondent and Notice of Hearing (the "Statement") regarding its involuntary closure of the pharmacy.

34. The Statement reiterated that due to the seizure of the pharmacy's computer and arrest of Igbinovia, "the pharmacy was left unable to operate in conformance with applicable law," but does not specify what "applicable law" applied or could not be complied with by Plaintiffs.

35. The Statement advised ACRX that on July 18, 2019, the Board would hold a hearing regarding its involuntary closure of ACRX, and that "ACRX will have the opportunity to show the Board that the pharmacy is now able to operate in conformance with Nevada law." Like the Notice of Involuntary Closure, the Statement also failed to provide ACRX with any notice of the laws, regulations, or other authorities allegedly violated, and deprived ACRX of notice of the allegations against it and an opportunity to meaningfully defend itself.

D. The Board's Ongoing Irreparable Harm Inflicted Upon the Plaintiffs.

36. Due to the Board's unauthorized and unlawful actions, Plaintiffs are prevented from conducting any business, including the distribution of controlled substances and engagement of any compounding activities, which has caused irreparable harm and threatens to totally destroy Plaintiffs' business.

37. The Board's unlawful closure of ACRX has caused other harm in the form of patients being unable to receive their medication. Because the Board completely shut Igbinovia and other employees out of ACRX, Plaintiffs have been unable to take desired steps to aid patients in finding other sources to fill their prescriptions.

38. Additionally, the Board's closure of ACRX has led to a slew of other harms, ranging from wholesalers cancelling their agreements with ACRX and debtors not paying ACRX, to the pharmacy being unable to receive and deposit payments necessary for ACRX's bills and

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utilities. ACRX's eight (8) employees also are affected by the Board's unjustified closure of the pharmacy. In short, the Board's closure and refusal to re-open ACRX has harmed, and is continuing to harm, every aspect of its operations.

39. The Board's continued closure of the Plaintiffs' business and refusal to allow Plaintiffs to conduct their business currently is causing irreparable harm; additionally, the Board's actions in prohibiting Plaintiffs to operate have adversely affected and harmed Plaintiffs' customers, some of whom include hospice and palliative care patients who rely on ACRX and Igbinovia to receive their life-saving prescription medication, including prescription refills.

40. The Board's unlawful closure of ACRX and disruption of Plaintiffs' business will force their customers to seek the services of other pharmacies to full their prescriptions and seek replacement services, and those customers will be lost indefinitely—not merely for the time ACRX is unlawfully closed based upon the Board's conduct.

41. Plaintiffs' loss of business, loss of commercial goodwill, and loss of customers to competing pharmacies constitutes irreparable harm, and one caused solely and proximately by the Board's failure to respect Plaintiffs' due process rights to notice and hearing before taking Plaintiffs' property rights.

42. Based on the Board's ad hoc treatment of Plaintiffs' right to conduct business and potential conditions for ACRX's reopening, any further proceedings prior to seeking judicial relief would be futile in the face of the irreparable harm caused by the Board's misconduct, which require emergency intervention by this Court.

FIRST CLAIM FOR RELIEF

(Declaratory Relief)

43. Plaintiffs hereby repeat, reallege, and incorporate all of the allegations contained in the preceding paragraphs as though fully set forth herein.

44. A true and ripe controversy exists between Plaintiffs and the Board as to whether the Board may continue to force the closure of Plaintiffs' business.

45. Specifically, a true and ripe controversy exists between Plaintiffs and the Board as to whether the Board is acting in excess of its authority and in violation of Nevada law in (a)

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effecting an involuntary closure of ACRX; (b) refusing to re-open ACRX without conditions or limitations based on the resolution of the circumstances the Board identified as requiring ACRX's involuntary closure; and (c) effecting a de facto taking of Plaintiffs' pharmacy licenses without proper notice or hearing under NRS 233B.121 and NRS 233B.127.

46. A true and ripe controversy exists between Plaintiffs and the Board as to whether the Board is entitled to "[c]losure as a result of action by the Federal Government" when the Government has not taken any action to suspend or revoke the ACRX's DEA Registration under 21 U.S.C. § 824 or 21 C.F.R. § 1301.36.

47. A true and ripe controversy exists between Plaintiffs and the Board as to whether the Board is entitled to deprive Plaintiffs from conducting their pharmacy business when neither Plaintiff has been convicted of any crime that would result in immediate suspension of their licenses under NRS 639.2121,[1] as neither Plaintiff has been convicted of any crime.

48. A true and ripe controversy exists between Plaintiffs and the Board as to whether the Board may close, and continue to keep closed, Plaintiffs' business without the filing of an Accusation to initiate suspension proceedings against either or both of them.

49. A true and ripe controversy exists between Plaintiffs and the Board as to whether the Board may close, and continue to keep closed, Plaintiffs' business without providing proper notice identifying the provisions of law allegedly violated by Plaintiffs in their pharmacy operations.

50. Declaratory relief is necessary to declare whether the Board is acting in excess of its authority and/or in violation of Nevada law in taking any of the actions described herein.

51. Declaratory relief is necessary to declare whether the Board's Notice of Involuntary Closure provided adequate notice to Plaintiffs regarding what statutes, regulations, or other authorities they purportedly were "unable to operate in conformance with" as alleged by the Board.

[1] "The conviction of any person who holds a certificate, license, registration or permit issued pursuant to this chapter of a felony for a violation of any federal law or law of any state concerning drugs or chemicals operates as an immediate suspension of the certificate, license, registration or permit." NRS 639.2121. "Conviction" is defined in NRS 639.006 as "a plea or verdict of guilty but mentally ill or a conviction following a plea of nolo contender to a charge of felony, any offense involving moral turpitude or any violation of the provisions of this chapter or chapter 453 or 454 of NRS."

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52. Declaratory relief is necessary to declare whether the Board is required to file a new Accusation and hold a hearing before taking any of the actions described herein.

53. Plaintiffs seek a declaration that the Board is acting in excess of its authority and/or in violation of Nevada law in taking the actions described herein, including (a) the closure of ACRX, (b) its refusal to re-open ACRX, and (c) its ad hoc negotiations regarding limits to be imposed on Plaintiffs as a condition of re-opening ACRX without notice or hearing.

54. Plaintiffs seek a declaration that the Board is required to file an Accusation and hold a hearing before taking any of the actions described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendant Board as follows:

55. For declaratory relief as described herein;

56. For a temporary restraining order, preliminary injunctive relief, and permanent injunctive relief enjoining the Board from its continued closure of ACRX, and further from preventing Plaintiffs from operating ACRX, including the compounding of drugs and distribution of controlled substances, in compliance with Nevada law; and

57. For such other and further relief as the Court deems just and proper.

DATED this 22nd day of July, 2019

HOLLAND & HART LLP

/s/ Constance L. Akridge

Constance L. Akridge
J. Malcolm DeVoy
Brittany L. Walker
9555 Hillwood Drive, 2nd Floor
Las Vegas, NV 89134
Attorneys for Plaintiffs

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EXHIBIT B

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DISTRICT COURT

CLARK COUNTY, NEVADA

ACRX SPECIALTY PHARMACY, INC. a Nevada corporation; and EGHOMWARE IGBINOVIA, a/k/a JERRY IGBINOVIA, an individual,

Plaintiffs,

v.

NEVADA STATE BOARD OF PHARMACY; DOES I-X; and ROE CORPORATIONS XI-XX,

Defendants.

Case No. A-19-798928-C
Dept. No. 2

EX PARTE MOTION FOR TEMPORARY RESTRAINING ORDER AND ORDER SETTING HEARING ON PRELIMINARY INJUNCTION AND

MOTION FOR PRELIMINARY INJUNCTION

HEARING REQUIRED
DATE: 7/26/19
TIME: 9:00 AM

Plaintiffs ACRX Specialty Pharmacy Inc. ("ACRX") and Eghomware Igbinovia, a/k/a Jerry Igbinovia ("Igbinovia"), collectively the "Plaintiffs," hereby apply to this Court for immediate issuance of a temporary restraining order and order setting hearing for preliminary injunction, and move for a preliminary injunction pursuant to Rule 65 of the Nevada Rules of Civil Procedure ("NRCP") and under Nevada Revised Statutes ("NRS") 33.010 against Defendant Nevada State Board of Pharmacy ("Board," or the "Defendant"). Plaintiffs specifically move this Court to enter an order:

1. Enjoining the Board from its continued enforcement of its putative "involuntary closure" of ACRX;
2. Enjoining the Board from denying Plaintiffs access to their place of business;
3. Enjoining the Board from prohibiting ACRX from conducting business as a licensed pharmacy;
4. Enjoining the Board from prohibiting Igbinovia from acting as a pharmacist; and
5. Enjoining the Board from prohibiting Plaintiffs from collectively operating as a pharmacy.

Upon filing, a copy of this Motion along with the Complaint will be provided immediately to Paul Edwards, Esq., general counsel for the Board.

This Motion is based upon the Complaint filed in this action, the Declaration of Constance L. Akridge, Esq. (the "Akridge Declaration") infra, the following Memorandum of Points and Authorities, and the exhibits attached hereto.

DATED this 22nd day of July, 2019

HOLLAND & HART LLP

/s/ Constance L. Akridge

Constance L. Akridge, Esq.
James M. DeVoy, Esq.
Brittany L. Walker, Esq.
9555 Hillwood Drive, 2nd Floor
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APPLICATION FOR ORDER SHORTENING TIME

Under Eighth Judicial District Court Rule 2.26, Plaintiffs apply for an Order Shortening Time in which the above Motion is to be heard based on the following Declaration of Plaintiffs' counsel.

DECLARATION OF J. MALCOLM DEVOY IN SUPPORT OF APPLICATION FOR ORDER SHORTENING TIME

I, James Malcolm DeVoy, declare as follows:

1. I am of counsel with the law firm Holland & Hart LLP and counsel of record for Plaintiffs in the above-captioned matter. On that basis, I have personal knowledge of the matters set forth in this declaration. I am over the age of 18 and competent to testify to the matters contained in this declaration if called to do so at trial.

2. Good cause exists for the Court to shorten the time for hearing Plaintiffs' Motion for Temporary Restraining Order and Order Setting Hearing on Motion for Preliminary Injunction (the "Motion") in this action. Plaintiffs have a reasonable likelihood of success on the merits of its Motion based on the Board's conduct depriving Plaintiffs of their property rights without due process. Specifically, the Board's actions have deprived and continue to deprive Plaintiffs of the ability to defend their property interests in their professional licenses issued and governed by the Board. Consequently, the Board's conduct has deprived Plaintiffs of their valid business interests and property rights inherent in their licenses.

3. Absent a temporary restraining order and preliminary injunction, Plaintiffs will suffer irreparable harm for which compensatory damages would not suffice. *See* NRS 33.010; *Boulder Oaks Cmty. Ass'n v. B & J Andrews Enters., LLC.*, 125 Nev. 397, 399, 215 P.3d 27, 28 (2009).

4. On June 20, 2019, the Board effected the involuntary closure of ACRX. According to the Board, involuntary closure was necessary given that the pharmacy was without a pharmacist when Igbinovia was arrested by federal authorities, and without access to its computer system after federal authorities seized ACRX's computer allegedly "rendering the pharmacy unable to operate in conformance with applicable law." However, ACRX was almost immediately able to continue to operate in conformance with applicable law since the very same day Igbinovia was processed

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and released on his own personal recognizance. In addition, ACRX regularly backed up its computer system and is able to immediately install a full archival copy of the information stored in the computer seized from ACRX.

5. Nevertheless, for nearly one month, the Board has refused to re-open Plaintiffs' pharmacy. As described in the Motion, the Board's reasons for depriving Plaintiffs of their property rights are not supported by applicable Nevada law and the Board failed to provide Plaintiff due process in violation of Nevada's Administrative Procedure Act.

6. Plaintiffs' pharmacy business remains closed due to the Board's unlawful acts. The immediate intervention of this Court is necessary to halt the ongoing loss of Plaintiffs' business based on the Board's conduct, and irreparable harm will continue without immediate judicial relief.

7. Because of the nature of the Motion, an Order Shortening Time is necessary due to Plaintiffs being irreparably harmed by the Board's unwarranted closure of Plaintiffs' business and deprivation of their license rights.

8. Additionally, if this matter were to be heard in the ordinary course, Plaintiff will continue to be irreparably harmed.

9. This request for an Order Shortening Time is made in good faith and without improper motive.

I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED this 22nd day of July, 2019 in Clark County, Nevada.

/s/ James Malcolm DeVoy
James Malcolm DeVoy, Esq.

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ORDER SHORTENING TIME

Based on the Declaration of Counsel filed and served herewith and based upon the Court's finding that good cause exists to have the instant Motion heard on shortened time, it is hereby ORDERED, that the time for the hearing of Plaintiffs' EX PARTE MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION ON ORDER SHORTENING TIME may be shortened to 9:00 (a.m.) / p.m. on the 26th day of July, 2019 before this Court.

Dated this 23rd of July, 2019

DISTRICT COURT JUDGE

Respectfully submitted by:

/s/ J. Malcolm DeVoy

Constance L. Akridge, Esq.
J. Malcolm DeVoy, Esq.
Brittany L. Walker, Esq.
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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' EX PARTE MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

I. INTRODUCTION

Plaintiffs filed this action because the Board has effectively stripped them of their licenses without due process. Acting far outside of its statutory authority, the Board relied on a regulation that prescribes what actions it must take after a pharmacy has been closed due to governmental action to unilaterally close ACRX, and further to deprive both Plaintiffs of the use of their Board-issued licenses. The Board did not before taking these actions provide Plaintiffs notice and opportunity to demonstrate compliance with Nevada law so that ACRX could continuously remain open. Indeed, the Board still has not instituted any formal proceedings against Plaintiffs, and has represented to Plaintiffs' counsel that the outcome of any such proceedings will result in the Board not allowing ACRX to reopen without substantial and business terminating restrictions (i.e. no controlled substances and no compounding). Akridge Decl. ¶¶ 6, 24 & 31.

During the Board's unlawful closure of ACRX, the Board purported to negotiate with Plaintiffs regarding the re-opening of their pharmacy while refusing to commence the proceedings needed to provide Plaintiffs with notice of their allegedly deficient conduct in the first place. The effect of the Board's actions is a complete and utter taking of Plaintiffs' property rights in their licenses without a shred of due process. Moreover, the Board's conduct reveals that it never intended to allow ACRX to re-open and needed only to delay Plaintiffs and ensure the death of their pharmacy business while the Board concocted an after-the-fact rationalization for its conduct.

For months, the Board has leveled a myriad of Kafka-esque allegations against Plaintiffs, but never elevated its allegations to an administrative action. Under NRS 639.241(1), the Board has authority to initiate an administrative action against a licensee only after filing an Accusation[1],

[1] NRS 639.241(2) defines an accusation as:

> The accusation is a written statement of the charges alleged and must set forth in ordinary and concise language the acts or omissions with which the respondent is charged to the end that the respondent will be able to prepare a defense. The accusation must specify the statutes and regulations which the respondent is alleged to have violated, but must not consist merely of charges phrased in language of the statute or regulation. The accusation must be signed by the Executive Secretary of the Board acting in his or her official capacity.

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providing notice of the alleged wrongful conduct to the licensee, and providing the licensee an opportunity to respond. The Board has never instituted an administrative action against **either** Plaintiff. Additionally, Neither the United States Department of Justice and Drug Enforcement Administration ("DEA") have commenced any action to suspend or revoke ACRX's DEA Registration.

Instead, the Board deemed ACRX to be "involuntarily closed" based on the temporary, less-than-24-hour unavailability of Igbinovia, its sole pharmacist / managing pharmacist, and based upon the misapprehension that ACRX did not have access to its pharmacy records. (In fact, and as ACRX apprised the Board, because of its backup system, Plaintiffs have full access to all of ACRX's records and can restore them imminently). Within hours, both Igbinovia and the data the Board required for the pharmacy to operate were available for ACRX to resume operations. Plaintiffs informed the Board immediately that they were able to resume operations, but the Board refused to allow ACRX to reopen, and instead engaged in dilatory conduct and sham negotiations intended to indefinitely prolong ACRX's closure. Each day ACRX remains closed, Plaintiffs' ability to continue operating ACRX is further jeopardized. Moreover, the Board's unjustified closure of ACRX has disrupted patients' access to critical medication, endangering public health and welfare. Involuntary closure of the pharmacy continues despite the Board possessing no basis under Nevada law for such closure.

As explained in this Motion, the futility of redressing the Plaintiffs' irreparable harm before the Board compels them to seek emergency injunctive relief to maintain the status quo and halt the irreparable harm the Board is causing their business. Unless enjoined by this Court, the Board will continue to use its power to strip the Plaintiffs of the benefits of their license and force their pharmacy business into an indefinite closure without any prior notice or hearing, just as it has done now. Without this Court's immediate relief, the Plaintiffs' business will be shut down indefinitely and cease to exist—and without a single allegation of wrongdoing made against them by the Board.

For these reasons, Plaintiffs request that the Court immediately enter a temporary restraining order and hold a hearing on a preliminary injunction in the Plaintiffs' favor within 14

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days of this Motion. Plaintiffs submit that the Court's order must provide the following relief to be effective and cease their ongoing irreparable harm:

1. Enjoining the Board from its continued enforcement of its putative "involuntary closure" of ACRX;
2. Enjoining the Board from denying Plaintiffs access to their place of business;
3. Enjoining the Board from prohibiting ACRX from conducting business as a licensed pharmacy;
4. Enjoining the Board from prohibiting Igbinovia from acting as a pharmacist; and
5. Enjoining the Board from prohibiting Plaintiffs from collectively operating as a pharmacy.

Plaintiffs seek only for the Court to restore it to the position it was before the Board abused its power and improperly closed their pharmacy business on June 20, 2019, and require the Board to allow Plaintiffs access to their business that the Board has denied them without any legitimate business.

II. STATEMENT OF FACTS

ACRX is a specialty compounding pharmacy in Las Vegas, Nevada, doing business within Clark County. ACRX holds pharmacy license number PH03673 issued by the Board, and as of July 18, 2019, ACRX's license is active. *See* ACRX's Pharmacy License attached as **Exhibit 1**. Igbinovia is the sole officer and director of ACRX, and is its sole pharmacist as well. Decl. of E. Igbinovia ("Igbinovia Decl.") at ¶ 1; *see also* ACRX's Nevada Secretary of State information attached as **Exhibit 2**. Igbinovia holds pharmacist license number 16316 issued by the Board, and as of July 18, 2019, Igbinovia's Board-issued license is active. *See* Igbinovia's Pharmacy License attached as **Exhibit 3**.

ACRX is a specialty pharmacy that compounds (i.e., makes from their constituent components) drugs that are not readily available for retail sale to pharmacies.[2] One of the drugs

[2] NAC 639 defines "compound" and "compounding" as "to form or create a composite product by combining one or more different ingredients." This definition is expanded upon in NAC 639.6625(1) to mean "preparation, mixing or assembling of a drug product of which at least one component is a prescription drug" and "packaging and labeling

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that Plaintiffs compounded was buprenorphine, a substance that aids individuals in treating and overcoming opioid addiction.[3] Despite this therapeutic value of buprenorphine, it is a Schedule III controlled substance[4] under federal law[5] and Nevada law.[6]

The Federal Controlled Substances Act defines a controlled substance as one that specifically has been scheduled as such. 21 U.S.C. § 802(6). Drugs that have been scheduled as controlled substances under federal law include alprazolam (Xanax)[7] and modafinil (sold under the name Provigil and used to treat shift sleep disorders).[8] In Nevada, buprenorphine's Schedule III status places it in the company of substances including chorionic gonadotropin (also known as HCG, frequently used as a dietary aid in the "HCG diet")[9] and naturally occurring hormones such as human growth hormone[10] and testosterone.[11] Despite their lawful conduct in compounding buprenorphine, Plaintiffs' compounding of controlled substances ultimately made it a target for the Board's unwarranted scrutiny.

A. ACRX's History with the Board and Other Governmental Authorities.

Beginning in at least December of 2018, the Board subjected Igbinovia and ACRX to enhanced and unwarranted scrutiny. Igbinovia Decl. ¶ 2. Due to the Board's instigation, the FDA appointed a monitor to observe and report on Plaintiffs' compounding pharmacy activities. *Id.* At the end of the FDA's observation of Plaintiffs, the FDA took no adverse action with respect to the Plaintiffs, their business operation, or any of their lawfully compounded pharmaceuticals. *Id.*

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incident to the preparation, mixing or assembling of a drug product for the purpose of selling or dispensing the drug product pursuant to a prescription or chart order."

[3] Buprenorphine is a medication approved to treat opioid dependency, and is permitted to be prescribed or dispensed in physician offices. Buprenorphine, Substance Abuse and Mental Health Services Administration, https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine (last accessed July 17, 2019).

[4] Schedule III controlled substances, such as anabolic steroids, are drugs the DEA considers having an accepted medical use and lower potential for abuse.

[5] 21 C.F.R. § 1308.13.

[6] NAC 453.530(14)

[7] 21 C.F.R. § 1308.14(c)(2).

[8] *Id.* § 1308.14(f)(7).

[9] NAC 453.530(7)(h).

[10] NAC 453.530(13).

[11] NAC 453.530(7)(kk).

Once the FDA ceased monitoring Plaintiffs' operations, the Plaintiffs believe and therefore aver that the Board worked in conjunction with the DEA to scrutinize and review Plaintiffs. ACRX possessed DEA Registration FA6553108, making him subject to the jurisdiction of the DEA.[12] The DEA then investigated Plaintiffs and their pharmacy operations. The DEA possesses broad powers to suspend and revoke DEA registrations. *See* 21 U.S.C. § 824; 21 U.S.C. § 1301.36. When the DEA finds that there is "imminent danger to the public health or safety," it may suspend a person's registration and order him or her to show cause why the license should not be revoked or suspended. 21 C.F.R. § 1301.36(e). The DEA, however, never instituted any suspension or revocation proceedings regarding the Plaintiffs. Igbinovia Decl. ¶ 11.

B. The Board's June 21, 2019 Notice of Involuntary Closure.

On June 20, 2019, despite the FDA and DEA taking no action to close ACRX or limit Igbinovia's pharmaceutical conduct, the United States Department of Justice unsealed an indictment naming Igbinovia as a defendant in a criminal action.

The government charged Igbinovia with several violations of the Controlled Substances Act, including 21 U.S.C. §§ 841(a)(1), (b)(1)(E), (b)(1)(E)(i), and 846. These unproven allegations against Igbinovia arose from ACRX's alleged provision of buprenorphine to four other individuals involved in a Las Vegas-area addiction recovery facility—including two doctors—with whom Igbinovia allegedly co-conspired. On June 20, 2019, federal law enforcement officers arrested Igbinovia and seized ACRX's nine (9) computers. *Id.* ¶ 4. That very same day, Igbinovia was arraigned, entered a plea of not guilty, and was released without any bond on his own recognizance after just hours in custody. *Id.* Despite this indictment, no federal agency has suggested that ACRX should be closed, taken action to cease ACRX's operations, or acted to suspend or revoke ACRX's DEA Registration.

On June 21, 2019, the Board's Office of the General Counsel issued a Notice of Involuntary Closure of Pharmacy and Right to Hearing (the "Notice of Involuntary Closure" attached as

[12] The DEA is referenced repeatedly throughout NRS Chapter 639, but most significantly, the status of a pharmacists' DEA registration controls his or her licensure by the Board, and even the temporary loss or suspension of DEA registration will result in the suspension of the individual's pharmacy license issued by the Board. NRS 639.2107.

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Exhibit 4) to Plaintiffs' counsel. The Notice of Involuntary Closure purported to close ACRX under NAC 639.570 because "federal law enforcement agents arrested [Igbinovia] and seized ACRX Specialty Pharmacy's computer system on June 20, 2019, rendering the pharmacy unable to operate in conformance with applicable law." *Id.* The Board never specified, whether in the Notice of Involuntary Closure or elsewhere, what "applicable law" Plaintiffs had violated. *Id.* By its own terms, the Notice of Involuntary Closure did not constitute the Board filing an Accusation, summary suspension, or formal investigation. *Id.*

Moreover, by the date of the Notice of Involuntary Closure, the two conditions the Board's General Counsel identified as bases for closure—Igbinovia's arrest and the seizure of ACRX's computer system—had been resolved. Igbinovia was released on his own recognizance and without restrictions on his ability to practice pharmacy. *Id.* Additionally, Igbinovia maintained a full and complete remote backup of all the information on the computers seized from ACRX, and stood ready, willing, and able to re-install them on new computers for the pharmacy. *Id.* The Plaintiffs could have re-opened the pharmacy at any time from June 21, 2019 onward, had the Board not unjustifiably prohibited them from doing so.

C. The Board's Refusal to Re-Open ACRX, Despite Having No Grounds to Close It.

On June 21, 2019, Igbinovia informed the Board that he was free on his own recognizance and had full backups for the data stored on the pharmacy's computers; as such, he was ready to re-open his pharmacy business immediately. *Id.* The Board refused to do so, and it maintained that ACRX was subject to an involuntary closure under NAC 639.570.

Almost two weeks later, on July 3, 2019, the Board sent a Notice of Hearing (the "July 3 Notice" attached as **Exhibit 5**) to Plaintiffs' counsel. The July 3 Notice did not specify what statutes or conduct were at issue or allegedly had been violated. Instead, the July 3 Notice stated, "The hearing pursuant to NRS 233B.121 to context ACRX Specialty Pharmacy's involuntary closure pursuant to NAC 639.570 for case number 19-044-PH-S has been scheduled" for July 18, 2019." Exhibit. 5.

Then, almost three weeks after the involuntary closure, on July 11, 2019, the Board issued a Statement to the Respondent and Notice of Hearing (the "Statement" attached as **Exhibit 6**)

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regarding its putative involuntary closure of ACRX. This Statement reiterated the Notice of Involuntary Closure, stating that Igbinovia's arrest and the seizure of ACRX's computers rendered it "unable to operate in conformance with applicable law," without further specification. *Id.* As its sole rationale for the ACRX's continued closure, the Statement identified NAC 639.570(5)(a), which specifies that involuntary closure exists "as a result of action by the Federal Government, the State of Nevada or the governing body of any county or city within the State of Nevada." Yet, even as of the date of the Statement, no such action by any of those entities had even been instituted, let alone yielded any kind of suspension, revocation, temporary restraining order, injunction, or other relief that would have ceased ACRX's operation. Igbinovia Decl. ¶ 11.

D. Despite Never Filing Accusations Against Plaintiffs, the Board Engages in Shifting Settlement Discussions to Re-Open the Improperly Closed Pharmacy.

To initiate any proceedings to revoke, suspend, limit, or condition any license it issues, the Board must first file an Accusation. NRS 639.241(1). At the time of ACRX's involuntary closure, the Board had not filed an Accusation against either of the Plaintiffs, and still has not done so through the time of this Motion's filing. Nonetheless, Plaintiffs immediately attempted to cooperate so that they could preserve their pharmacy's reputation and avoid litigation. Plaintiffs and their counsel entered negotiations with the Board and its General Counsel to re-open ACRX, and resume serving their patients as Plaintiffs were receiving calls from patients seeking refills of critical medication for serious and even life-threatening conditions. Plaintiffs attempted to reach this resolution with the Board's General Counsel even though the Board had not filed any Accusation necessary to limit, suspend, or revoke their licenses. NRS 639.241(1).

In the course of these discussions, the Board's General Counsel stated that the Board would be agreeable to restoring Plaintiffs' access to the pharmacy location in exchange for their commitment to not possess or distribute controlled substances. *See* emails between the Board and Plaintiffs dated July 2, 2019 attached as **Exhibit 7**. By July 2, 2019, Plaintiffs and their attorneys negotiated with both the DEA and the Board regarding the mechanics of suspending ACRX's active DEA Registration without it adversely affecting their Board-issued licenses. *Id.*

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By early July of 2019, the Plaintiffs had nearly resolved the issues regarding Plaintiffs' possession and distribution of controlled substances as a condition of re-opening ACRX. On July 11, 2019, the Board suddenly and inexplicably shifted goalposts: the Board would only allow ACRX to re-open if Igbinovia refrained from compounding, and sold only prescription drugs that were pre-packaged and obtained from manufacturers and their distributors. *See* emails between the Board and Plaintiffs dated July 11, 2019 attached as **Exhibit 8**. As ACRX is a compounding pharmacy, the Board's offer amounted to little more than remaining open in name only.

When discussing this offer, the Board's General Counsel conceded that the Board had not filed any Accusation against the Plaintiffs. *See* **Exhibit 8**. On the basis that the Accusations had not been filed, the Board then refused to discuss the contents of their allegations against either of the Plaintiffs, and refused to share any information regarding the challenged conduct, such as its approximate time of occurrence or the substance of the grievance.

Plaintiffs spent weeks attempting to negotiate the re-opening of ACRX with the Board, which had held the pharmacy's existence hostage without any legal authority to do so.[13] Seemingly upon the eve of a final agreement between the Plaintiffs and the Board, the Board changed its parameters and sought to impose new demands and restrictions on Plaintiffs. The Board admittedly based its change in position upon conduct the Board refused to identify, and premised on Accusations it had never filed.[14] With the very existence of their business in imminent danger and any illusion of due process before the Board irretrievably shattered, Plaintiffs have filed suit seeking declaratory and injunctive relief (*see generally,* Complaint filed herewith) and now move this Court for emergency relief.

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[13] Plaintiffs' current counsel informed the Board that its Notice of Involuntary Closure, July 3 Notice, and Statement did not provide satisfactory notice of the July 18 hearing. Akridge Decl. ¶ 30-33. Plaintiffs' counsel then sent a confirmatory letter on July 18, 2019, attached as Exhibit 10. On July 19, 2019, the Board responded through a letter from its General Counsel, attached as Exhibit 11, reiterating the Board's prior arguments. Although the Plaintiffs had never agreed for ACRX to remain closed at any time, and under any circumstances, the Board falsely claimed that ACRX agreed to remain closed pending a further hearing date. Igbinovia Decl. ¶ 10; Exhibit 11.

[14] In the meantime, it appears the Board busied itself with disparaging Plaintiffs to third parties, including its landlord. As seen in Exhibit 12, the Board took it upon itself to on June 20, 2019, to notify ACRX's landlord that the pharmacy had been raided and its owner arrested, but apparently did not provide an update when Igbinovia had been released from custody. Igbinovia Decl. ¶ 6. Plaintiffs know of no legal authority that would permit the Board, let alone make it incumbent upon them, to alert ACRX's landlord of this development.

III. LEGAL ARGUMENT

A. Legal Standard to Issue a Temporary Restraining Order and Preliminary Injunction.

Nevada Rule of Civil Procedure 65(b) authorizes the Court to issue a temporary restraining order in order to avoid irreparable harm prior to a hearing on a preliminary injunction. A temporary restraining order serves to maintain the status quo pending a hearing on the movant's application for a preliminary injunction. *Granny Goose Foods, Inc. v. Brotherhood of Teamsters & Auto Truck Drivers*, 415 U.S. 423, 439 (1974). The Court's decision to issue a temporary restraining order is based on the same factors evaluated when entering a preliminary injunction. *See Stuhlbarg Int'l Sales Co., Inc. v. John D. Brush & Co., Inc.*, 240 F.3d 832, 839 (9th Cir. 2001); *Ottenheimer v. Real Estate Division*, 91 Nev. 338, 535 P.2d 1284 (1975); *see also News Herald v. Ruyle*, 949 F. Supp. 519, 521 (N.D. Ohio 1996) ("If there is notice to the other side and a hearing, the Court applies the same standards governing issuance of a preliminary injunction in determining whether to issue a temporary restraining order").

Injunctive relief in the form of a temporary restraining order and preliminary injunction is available when "acts committed without just cause [...] unreasonably interfere with a business or destroy its credit and profits," such as interference with the business's operation through the wrongful disclosure of confidential information. *Sobol v. Capital Mgmt. Consultants, Inc.*, 102 Nev. 444, 446, 726 P.2d 335, 337 (1986). The Court may enter a preliminary injunction where an applicant can show a likelihood of success on the merits of their claims, and a reasonable probability that the non-moving party's conduct, if not stopped, will cause irreparable harm. *Clark Cnty. Sch. Dist. v. Buchanan*, 112 Nev. 1146, 1149, 924 P.2d 716, 719 (1996); *see* NRS 33.010 (describing circumstances where "[a]n injunction may be granted"). The Court "may also weigh the public interest and the relative hardships of the parties in deciding whether to enter a preliminary injunction." *Buchanan*, 112 Nev. at 1149, 924 P.2d at 719.

The purpose for the Court's entry of a preliminary injunction is to maintain the status quo and avoid irreparable harm until the dispute's matters may be fully heard. *Dixon v. Thatcher*, 103 Nev. 414, 415, 742 P.2d 1029, 1029 (1987). Where a wrong has been committed, the Court may

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enter an injunction to restore the status quo and undo any harms caused by the non-movant's wrongful acts. *Memory Gardens of Las Vegas, Inc. v. Pet Ponderosa Memorial Gardens, Inc.*, 88 Nev. 1, 3, 492 P.2d 123, 124 (1972); *see Leonard v. Stoebling*, 102 Nev. 543, 550, 728 P.2d 1358, 1363 (1986). This preservation of the status quo is of particular significance where the movant faces irreparable harm for which legal remedies are inadequate. *See Arcamuzi v. Continental Air Lines*, Inc., 819 F.2d 935, 937 (9th Cir. 1987).

B. A Temporary Restraining Order and Preliminary Injunction are Necessary to Enjoin the Board's Improper and Impermissible Closure of ACRX, Halt Irreparable Harm Caused to Plaintiffs by the Board's Actions.

The Board has supplanted the authority granted it by the legislature in NRS Chapter 639 with its own unreviewable, ad hoc adjudicatory process that has indefinitely closed Plaintiffs' pharmacy business. As a statutory creation, the Board is bound to the limitations of the laws that created it and may not pick and choose which authorities it wishes to be bound by. *See Clark Cty. Sch. Dist. v. Clark Cty. Classroom Teachers Ass'n*, 115 Nev. 98, 102, 977 P.2d 1008, 1010 (1999) ("the powers of an administrative agency are limited to those powers specifically set forth by statute.") The Board must be bound by all the Nevada laws that apply to it, and not merely those the Board prefers. *Id.*

This Court's injunctive powers are required to enforce this fundamental premise. *Id.* at 103, 977 P.2d at 1011 ("the court may not confer upon an administrative agency power in excess of that authorized by the legislature."). This Court's entry of a Temporary Restraining Order and Preliminary Injunction are necessary in this case. Plaintiffs (1) are likely to succeed on the merits of their claim that the Board exceeded its authority by shutting down ACRX and depriving Plaintiffs of the use of their State-issued license without proper notice, hearing, or any safeguards approximating due process; (2) will suffer irreparable harm absent court intervention, (3) there is no adequate legal remedy, and (4) the public interest and balance of hardships weigh in favor of Plaintiffs. The Board should therefore be enjoined from enforcing the closure of ACRX and its de facto taking of Plaintiffs' pharmacy licenses.

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1. The Plaintiffs Enjoy a Reasonable Likelihood of Success on the Merits of their Claims Against the Board.

To obtain injunctive relief, Plaintiffs must show they possess a reasonable likelihood of success on the merits of their claims against the Board. A "reasonable probability of success on the merits" requires a plaintiff to demonstrate both the existence of its claim (or claims) against the defendant and a likelihood of prevailing on that claim. *See, e.g., State Farm Mut. Auto. Ins. Co. v. Jafbros Inc.*, 109 Nev. 926, 928, 860 P.2d 176, 178 (1993); *See Dixon*, 103 Nev. at 415, 742 P.2d at 1029.

Plaintiffs possess a property license in their respective licenses issued and governed by the Board, and Plaintiffs' rights cannot be limited, reduced, or taken away by the Board without adequate due process. A state-issued license "that can be revoked 'for cause' creates a property interest." *Thornton v. City of St. Helens*, 425 F.3d 1158, 1164 (9th Cir. 2005). As such, "licenses are not to be taken away without that procedural due process required by the Fourteenth Amendment." *Bell v. Burson*, 402 U.S. 535, 539 (1971).

Plaintiffs seek only the Court's declaration that the Board's actions violated the Administrative Procedure Act and its own statutory and regulatory authority. *See generally*, Compl. This Court is entitled to provide declaratory relief to Plaintiffs under NRS 30.030:

> Courts of record within their respective jurisdictions shall have power to declare rights, status and other legal relations whether or not further relief is or could be claimed. No action or proceeding shall be open to objection on the ground that a declaratory judgment or decree is prayed for. The declaration may be either affirmative or negative in form and effect; and such declarations shall have the force and effect of a final judgment or decree.

As set forth below, Plaintiffs have every reason to prevail in their request for a declaration that the Board's conduct has violated their rights.

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a) The Board's Actions to Close the Pharmacy Fail to Comply with NRS 233B.121 & 233B.127 and are Invalid; as such, the Board's Ongoing Closure of ACRX Violates Both Nevada Law and Plaintiffs' Due Process Rights.

The Board's closure of ACRX reverses the fundamental order of due process: notice, then action.[15] Instead, the Board acted to close ACRX first. Then, only after that closure, the Board provided Plaintiffs with notice that they could attempt to re-open the pharmacy by addressing the Board's unintelligible concerns about compliance with unspecified laws. A comparison of the notices and statements issued by the Board against relevant law reveals the numerous and profound deficiencies within the Board's process, and why Plaintiffs must prevail in their claims for declaratory relief.

Although the Board is required to provide notice by certified mailing the form of an Accusation before taking action against a licensee under,[16] it failed to do so. As such, it violated the Administrative Procedure Act, which requires prior notice to the licensee:

> No revocation, suspension, annulment or withdrawal of any license is lawful unless, before the institution of agency proceedings, the agency gave notice by certified mail to the licensee of facts or conduct which warrant the intended action, and the licensee was given an opportunity to show compliance with all lawful requirements for the retention of the license

NRS 233B.127(3).

Similarly, the Administrative Procedure Act specifies the information that must be provided in such notice for it to comport with due process:

> 1. In a contested case, all parties must be afforded an opportunity for hearing after reasonable notice.
> 2. The notice must include:
> (a) A statement of the time, place and nature of the hearing.

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[15] This basic premise of due process is encoded in the Administrative Procedure Act, found within NRS Chapter 233B. When adopting the Administrative Procedure Act, the Legislature stated that the Act's purpose was to "establish minimum procedural requirements for the regulation-making and adjudication procedure of all agencies of the Executive Department of the State Government[.]" NRS 233B.020. Yet, as explained herein, the Board has failed to satisfy even these "minimum procedural requirements"

[16] Nevada law specifies that any hearing affecting a license issued by the board "must" be initiated by the filing of an Accusation. NRS 639.241(1)

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> (b) A statement of the legal authority and jurisdiction under which the hearing is to be held.
> (c) A reference to the particular sections of the statutes and regulations involved.
> (d) A short and plain statement of the matters asserted. If the agency or other party is unable to state the matters in detail at the time the notice is served, the initial notice may be limited to a statement of the issues involved. Thereafter, upon application, a more definite and detailed statement must be furnished.

NRS 233B.121.

As a threshold matter, the Board has not filed any Accusation against Plaintiffs, which is required to initiate any proceedings limiting or suspending their licenses. NRS 639.241. The Board's failure to provide its own form of required notice demonstrates its failure to comply with NRS 233B.121 and 233B.127.

i. NRS 233B.127 Provides Plaintiffs with Increased Protections of the Property Rights Inherent in Their Licenses, and the Board Disregarded those Protections.

The Board's refusal to re-open ACRX, and refusal to allow Igbinovia to work as ACRX's pharmacist, operates as a complete taking of Plaintiffs' license rights and thus implicates NRS 233B.127.[17] Due to the property rights inherent in licenses issued by the State, NRS 233B.127

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[17] NRS 233B.127 Licenses: Applicability of provisions governing contested cases to grant, deny or renew; expiration notice and opportunity to show compliance required before adverse action by agency; summary suspension.

1. The provisions of NRS 233B.121 to 233B.150, inclusive, do not apply to the grant, denial or renewal of a license unless notice and opportunity for hearing are required by law to be provided to the applicant before the grant, denial or renewal of the license.

2. When a licensee has made timely and sufficient application for the renewal of a license or for a new license with reference to any activity of a continuing nature, the existing license does not expire until the application has been finally determined by the agency and, in case the application is denied or the terms of the new license limited, until the last day for seeking review of the agency order or a later date fixed by order of the reviewing court.

3. No revocation, suspension, annulment or withdrawal of any license is lawful unless, before the institution of agency proceedings, the agency gave notice by certified mail to the licensee of facts or conduct which warrant the intended action, and the licensee was given an opportunity to show compliance with all lawful requirements for the retention of the license. If the agency finds that public health, safety or welfare imperatively require emergency action, and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action. An agency's order of summary suspension may be issued by the agency or by the Chair of the governing body of the agency. If the order of summary suspension is issued by the Chair of the governing body of the agency, the Chair shall not participate in any further proceedings of the agency relating to that order. Proceedings relating to the order of summary suspension must be instituted and determined within 45 days after the date of the order unless the agency and the licensee mutually agree in writing to a longer period.

applies to proceedings affecting licenses and provides additional due process protections for Nevadans holding licenses issued by the State. Significantly, NRS 233B.127(3) provides that **before** a license is suspended, the licensee must be provided notice by certified mail of the " . . . facts or conduct which warrant the intended action and the licensee must be given an opportunity to show compliance with all lawful requirements for retention of the license."

The Board never complied with this advance notice requirement before closing ACRX and refusing to permit its re-opening. Prior to the Notice of Involuntary Closure, the Board never provided: (i) any notice to Plaintiffs of its anticipated action, (ii) facts or conduct which warranted the Board's intended action, and (iii) an opportunity to show compliance with all lawful requirements for retention of the license. In addition to these procedural defects, the substance of the Board's communications failed to warrant an unnoticed taking of Plaintiffs' licenses. Nothing within the Notice of Involuntary Closure, or any other documentation generated by the Board, indicates that ACRX's operation or Igbinovia's continued practice as a pharmacist, constituted any threat to public health, safety, or welfare.[18]

Additionally, the Board's conduct and steadfast refusal to acknowledge Plaintiffs remedied the only two stated reasons for ACRX's closure—Igbinovia's absence and the seizure of ACRX's computers—further violated NRS 233B.127. Nevada law requires that the Board give its licensees "an opportunity to show compliance with all lawful requirements for retention of the license." While the Notice of Involuntary Closure, July 3 Notice, and Statement all were deficient in stating what statutory or regulatory provisions the Plaintiffs allegedly violated, the Board disregarded its own rules and ignored Plaintiffs' repeated showings that they had corrected the alleged deficiencies[19] within the Notice of Involuntary Closure. Igbinovia Decl. ¶ 7.

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[18] Presumably if it had, the DEA would have first acted to suspend, revoke, or restrict ACRX's DEA Registration on an expedited basis as specifically provided in 21 C.F.R. § 1301.36.

[19] The Board is statutorily allowed to adopt regulations regarding "the use of computerized mechanical equipment for the filling of prescriptions." NRS 639.070(1)(o). The Board's regulations require that these systems comply with the provisions of NAC 639.910 through 639.935, and that computerized pharmaceutical records be maintained for a period

Nothing within the Notice of Involuntary Closure, July 3 Notice, or Statement satisfy the requirements of NRS 233B.127 for the Board to limit Plaintiffs' licenses in any way, and the Board refused to provide Plaintiffs the statutorily mandated opportunity to show their compliance with applicable law. Any action the Board took to restrict Plaintiffs' pharmacy activities on an expedited basis is therefore invalid under Nevada law and necessarily violates Plaintiffs' due process rights.[20] The only basis on which the Board could have pursued Plaintiffs in compliance with the Administrative Procedure Act is under NRS 233B.121, which also fails for the reasons set forth below.

ii. The Board's *De Facto* Taking of Plaintiffs' Licenses Failed to Comply with the Provisions of NRS 233B.121 and Further Violated Plaintiffs' Rights.

The Nevada Supreme Court has long recognized the importance of eliminating "unfair surprise" from the administrative process, and that "adequate opportunity to prepare" in response to a notice required by NRS 233B.121 is "crucial" to due process. *Nevada State Apprenticeship Council v. Joint Apprenticeship & Training Comm. for Elec. Indus.*, 94 Nev. 763, 765, 587 P.2d 1315, 1316–17 (1978); *see also Coury v. Whittlesea-Bell Luxury Limousine*, 102 Nev. 302, 307, 721 P.2d 375, 378 (1986). In *Clark County School District v. Bundley*, the Nevada Supreme Court held that a hearing notice that merely stated the issue as whether the respondent was discharged for misconduct was not adequate because the respondent was not fully aware what misconduct she allegedly committed. 122 Nev. 1440, 1448, 148 P.3d 750, 756 (2006). The same deficiencies that

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of two years from the date of dispensing medication, and available for inspection by the Board. NAC 639.2977. The Board must approve the use of the computer system implemented within any pharmacy, and shall approve of computer systems that, among other things, maintain records of each prescription issued using the computer system, maintains copies of the prescriptions fulfilled by the pharmacy, and prohibits modification of the prescription. NAC 639.7102(2)(e), (4)(b). The Board previously approved of ACRX's computer system under NAC 639.7102, including its compliance with NAC 639.910 through 935. Plaintiffs are in possession of all of the records and software the Board previously approved for use, curing the deficiency the Board identified in its Notice of Involuntary Closure; the Board has inexplicably refused to acknowledge this cure of the defect it relied upon to unjustifiably close ACRX. The Board's refusal to recognize ACRX's past compliance with the Board's standards, as well as ACRX's willingness and ability to do so once its wrongful exclusion from its pharmacy facility is concluded, further violates NRS 233B.127's requirement that the Board provide Plaintiffs an opportunity to show their compliance with applicable law.

[20] Even if the Board sought to summarily suspend Plaintiffs' licenses under the process contemplated in NRS 233B.127, the Board still would need to file an Accusation against Plaintiffs to do so under NRS 639.241(1), which it failed to do.

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the Supreme Court rejected in *Bundley* are present throughout the Board's notices and correspondences in this case.

Although the Notice of Involuntary Closure, July 3 Notice, and Statement do not constitute the Accusations necessary for the Board to limit the Plaintiffs' licenses, even if they are liberally construed as notice by the Board, they fail to meet the standards of NRS 233B.121. In particular, the Notice of Involuntary Closure, July 3 Notice, *and* Statement all fail to refer to specific statutes or violations that the Board contends the Plaintiffs violated. **Exhibits 4-6**. While the Board faults Plaintiffs for failure or inability "to operate in conformance with applicable law," the Board never specifies what those laws are. *Id.* Instead, Plaintiffs are left with the impossible task of disproving its violations of laws and regulations that the Board never identifies. *See* NRS 233B.121(2)(c).

The vague and cursory nature of the Notice of Involuntary Closure, July 3 Notice, and Statement preclude them from complying with NRS 233B.121(2)(d) as well. Despite the passage of three weeks from the Notice of Involuntary Closure to the Statement, and frequent communication with Plaintiffs to develop the background facts involved in ACRX's closure, the Board never offers more than an assertion that Igbinovia's arrest and the seizure of ACRX's computers rendered them unable to operate "in conformance with applicable law." **Exhibits 4-6**.

This summary does not establish the "matters asserted" by the Board, or explain how or why they constitute any violation of the laws and regulations the Board is tasked to enforce. The Board's description of events identifies a specific event, but not the "matters asserted" by the Board; instead, the Board's Notice of Involuntary Closure, July 3 Notice, and Statement do nothing more than identify specific incidents, but fail to identify what issues the Board takes with them, and how they constitute a matter within the Board's jurisdiction.

The vague and non-specific nature of the Board's communications to Plaintiffs and Plaintiffs' counsel illustrate the futility of proceeding with any hearing the Board may have scheduled. The Board did not specify which statutes or regulations Plaintiffs were accused of violating. Similarly, the Board did not specify how Plaintiffs' alleged conduct or actions—including the unproven claims against them filed by the United States—would have violated any such authorities. The involuntary closure provision is not triggered by the facts the Board relies

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upon to conduct the involuntary closure. The Board presented Plaintiffs with a no-win scenario: appear before the Board to defend unspecified conduct against violations of unknown legal authorities against the backdrop of the Board's promises of future closure, or to fail to appear and face the exact same consequences. Akridge Decl. ¶ 30.

The Board's wholly insufficient notices to Plaintiffs provide no more than a smokescreen for its *ad hoc* decision-making and *post hoc* rationalization for trampling Plaintiffs' due process rights. This is exactly the kind of arbitrary enforcement and application of the law that the Administrative Procedure Act prohibits. *See* NRS 233B.020. The Board's conduct violates NRS 233B.121 and 233B.127, and entitles Plaintiffs to declaratory relief in their favor.

b) Similarly, the Board's Reliance on NAC 639.570 Is Baseless: No Federal or State Authority Has Acted to Close ACRX, and the Regulation Does Not Give the Board the Indefinite Closure Powers that the Board Now Claims.

The sole legal authority the Board cites for its closure of ACRX, NAC 639.570, does not support the Board's June 20, 2019 involuntary closure much less the Board's failure to allow reopening even though it knows ACRX is not without a managing pharmacist or its records. The Board should have rescinded its involuntary closure order no later than June 21, 2019. The Board's reliance on this regulation originates from the flawed premise that ACRX is subject to an "involuntary closure" under NAC 639.570(5)(a) stating, "[a]s used in this section, 'involuntary closure' of a pharmacy includes: (a) Closure as a result of action by the Federal Government, the State of Nevada or the governing body of any county or city within the State of Nevada[.]"

No governmental authority has closed ACRX. Indeed, the Board concedes that it has not filed a single Accusation against ACRX or Igbinovia, which would be required for the Board to suspend or revoke the license of either. Akridge Decl. ¶ 26; **Exhibit 8**. Moreover, federal authorities—while certainly having the power to do so if they wished—have not acted to revoke the DEA Registration needed to operate ACRX. *See* 21 U.S.C. § 824; 21 C.F.R. § 1301.36. Igbinovia Decl. ¶ 11. No other action, order, injunction, or other determination exists that could constitute an involuntary closure of ACRX under NAC 639.570. *Id.*

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Moreover, the Board's reliance on its regulation NAC 639.570 stretches the regulation's purpose far past its breaking point. The plain language of NAC 639.570 does not provide the Board with the authority to close the pharmacy. Instead it merely explains what the Board may do in the event a Pharmacy is involuntarily closes.[21]

While NAC 639.570 prescribes certain procedures for the Board to follow in the event of an involuntary closure, it does not vest the Board with discretion to involuntary close or keep a pharmacy closed indefinitely—especially when an event constituting an "involuntary closure" has not occurred. Thus, the entire framework for the Board's conduct and refusal to re-open ACRX is erroneous beyond repair. The only equitable resolution is for this Court to enjoin the Board's illegitimate closure of ACRX and, if the Board wishes to pursue the Plaintiffs, do so with the proper procedures and due process protections promised to them by law.

c) The Board Further Violated Plaintiffs' Rights by Disregarding ACRX's Right to Appoint a New Managing Pharmacist.

Although Igbinovia was ACRX's sole pharmacist, his arrest does not limit or preclude ACRX's continued operations as a duly licensed pharmacy. Nevada law requires that a pharmacy have a managing pharmacist on duty during the time the pharmacy is open to the public,[22] but does not impose any requirement that the managing pharmacist be an owner, director, officer, or hold

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[21] NAC 639.570 Involuntary closure of pharmacy. (NRS 639.070)

1. Upon an involuntary closure of a pharmacy, the licensee shall immediately surrender to the Board all controlled substances and dangerous drugs, and all order forms therefor, which are owned or controlled by the licensee on the premises of the pharmacy. A member of the Board or one of its inspectors shall immediately take possession of and hold all such substances, drugs and forms.

2. The controlled substances, dangerous drugs and forms so surrendered will be held in trust by the Board for the licensee. The substances and drugs so held will forthwith be inventoried, packaged, sealed and stored at the expense of the licensee in a place determined by the Board to be appropriately secure.

3. A licensee has 60 days after the effective date of the involuntary closure to make arrangements for the lawful sale or other disposition of the controlled substances and dangerous drugs so inventoried and stored. If no such sale or disposition is made by the licensee within the 60-day period, the Board will make arrangements for the sale or other disposition of the substances and drugs for the benefit of the licensee, and will account for them to the licensee. Upon disposition of the substances and drugs, the order forms will be returned to the Drug Enforcement Administration.

4. The licensee shall cooperate with the Board to promote the efficient administration of this section.

5. As used in this section, "involuntary closure" of a pharmacy includes:

(a) Closure as a result of action by the Federal Government, the State of Nevada or the governing body of any county or city within the State of Nevada;

(b) The revocation or suspension of any license issued to a pharmacy by the Board; or

(c) Any other involuntary closure, including an involuntary adjudication of bankruptcy, an appointment of a receiver or an entry of an order of closure by a court of competent jurisdiction.

[22] NRS 639.220(1); NAC 639.465.

an equivalent position within the pharmacy. A "managing pharmacist" is defined in NRS 639.0087 to be "a registered pharmacist who is responsible for the operation of a pharmacy." Any pharmacy's managing pharmacist may be changed with notice to the Board. NRS 639.220(4).

Despite Plaintiffs' correspondence to the Board, it has never explained its failure to consider these regulations in closing ACRX due to Igbinova's arrest. At minimum, this disregard of the Board's own regulations is voidable, and indicative of its impermissible, arbitrary treatment of ACRX and Igbinova in a manner dissimilar to other licensees. "An agency may not, for example, depart from a prior policy *sub silentio* to simply disregard rules that are still on the books." *Conservation Counsel for Haw. v. Nat'l Marine Fisheries Serv.*, 154 F. Supp. 3d 1006, 1033 (D. Haw. 2015), *citing U.S. v. Nixon*, 418 U.S. 683, 696 (1974). Nothing in the Board's communications to Plaintiffs or their counsel so far shows that the Board has even considered this issue, or has any explanation for why ACRX was closed without any opportunity to retain an alternate managing pharmacist.

2. Plaintiffs Are Suffering and Will Continue to Suffer Irreparable Harm Unless the Court Grants Injunctive Relief.

The total loss of one's business is an irreparable harm that may be remedied with injunctive relief. "The right to carry on a lawful business without obstruction is a property right, and acts committed without just cause or excuse which interfere with the carrying on of plaintiffs business or destroy its custom, its credit or its profits, do an irreparable injury and thus authorize the issuance of an injunction." *Guion v. Terra Mktg. of Nev., Inc.*, 90 Nev. 237, 239, 523 P.2d 847, 848 (1974). Acts committed without just cause which unreasonably interfere with a business or destroy its credit or profits may cause an irreparable injury. *Sobol*, 102 Nev. at 446, 726 P.2d at 337.

Nevada law recognizes that the loss of a state-issued license constitutes irreparable harm. "A licensee whose license has been revoked or suspended immediately suffers the irreparable penalty of loss of [license] for which there is no practical compensation. *State, Dept. of Bus. & Indus., Fin. Institutions Div. v. Nevada Ass'n Services, Inc.,* 128 Nev. Adv. Op. 34, 294 P.3d 1223, 1228 (2012) (*quoting Com. v. Yameen*, 401 Mass. 331, 516 N.E.2d 1149, 1151 (1987)). Irreparable

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harm exists when an entity is unable to continue conducting its business and is "threatened with the prospect of losing its license to conduct business." *Id.*

Plaintiffs have not merely been deprived of the use of their licenses, but this loss has come at the Board's hands, without a legally required notice or hearing to dispute the allegations against them. Indeed, the Board's conduct gives rise to two separate and discrete forms of irreparable harm: Plaintiff's loss of their pharmacy business, and the intractable harm caused by the Board's violation of their due process rights.

Loss of business in a manner that defies calculation and constitutes irreparable harm is readily recognized in Nevada's decisional authority. *Sobol*, 102 Nev. at 446, 726 P.2d at 337. The Board's closure of ACRX has been total. Plaintiffs have been prohibited from even entering the property occupied by ACRX. The viability of ACRX has been imperiled by the Board's actions, and its ongoing activities have ceased entirely. Despite the Board's closure of the business, Plaintiffs continue to receive calls from patients who seek refills of critical medication for serious and even life-threatening conditions, whose future use of the pharmacy is thrown into jeopardy due to the Board's improper actions.

Simultaneously, the Plaintiffs being deprived of use of their licenses while the Board runs roughed over their rights represents a different, but no less severe, form of irreparable harm. *See State, Dept. of Bus. & Indus., Fin. Institutions Div*, 294 P.3d at 1228. Plaintiffs' intangible rights as licensees subject to the Board's authority have been damaged and can only be restored by this Court's order instructing the Board to comply with the provisions of NRS Chapters 639 and 233B. The Board's proceedings so far, from closing down Plaintiffs' pharmacy on little more than its say-so to effectively revoking the Plaintiffs' licenses without filing a single Accusation, are inimical to the principle of due process and require this Court's intervention.

3. Plaintiffs Have No Adequate Legal Remedy Short of This Court's Immediate Injunction.

As the loss of an entire business constitutes irreparable harm, it axiomatically cannot be remedied with legal damages and mere monetary relief. *See Guion*, 90 Nev. at 239, 523 P.2d at 848. The Nevada Supreme Court has recognized that "harm is irreparable if it cannot be

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adequately remedied by compensatory damages." *Hamm v. Arrowcreek Homeowners' Ass'n*, 124 Nev. 290, 297, 183 P.3d 895, 901 (2008). The deprivation of Plaintiffs' use of their Board-issued licenses without proper notice and hearing creates a fundamental harm that cannot be remedied with compensation.

Despite there being no proceedings instituted by the DEA and no Accusations filed by the Board, it has refused to allow Plaintiffs to use their licenses. Akridge Decl. ¶ 6. The Board has inexplicably prohibited the Plaintiffs from re-opening ACRX even after satisfying the conditions specified by the Board as a condition of doing so. *Id.*; Igbinovia Decl. ¶ 7; **Exhibits 7-8**. By depriving the Plaintiffs of their property rights without a scintilla of due process, the Board has deprived them of any relief they could obtain short of this Court's entry of an injunction. Not only are legal damages inadequate for Plaintiffs' losses, but the Board's refusal to provide them with due process prior to stripping them of the powers inherent in their licenses show that anything short of this Court's relief as requested in the Motion is futile. Each day ACRX remains closed, Plaintiffs continue to experience irreparable harm and are less likely to resume their pharmacy business.

4. The Public Interest and Balance of Hardships Favor this Court Granting Plaintiffs Injunctive Relief and Allowing them to Operate Their Pharmacy.

The balance before the Court is whether the hardship borne by the Plaintiffs and their patients. This Court's calculation of the parties' relative hardships in granting an injunction should be a straightforward one. *Univ. & Cmty. Coll. Sys. of Nev. v. Nevadans for Sound Gov't*, 120 Nev. 712, 721, 100 P.3d 179, 187 (2004). Other courts have considered requests for injunctive relief where patient care could be affected, and found that their needs factor into the evaluation of the public interest. *See O'Bannon v. Town Court Nursing Center*, 447 U.S. 773, 778 n. 6 (1980)(The public has a "strong interest" in care of patients requiring treatment); *see also Navajo Health Found v. Burwell*, 100 F. Supp. 3d 1122, 1190 (D.N.M. 2015) ("To force those patients to go to other facilities at much greater distances is not in the public interest.").

Here, this dispute affects patients who are not parties to this action, but are affected and have had their access to medication disrupted by the Board's unjustified closure of ACRX.

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Akridge Decl. ¶27. Those affected patients' needs for prescribed, necessary medication is the most relevant measure of the public's interest in any injunctive relief, and weigh in favor of enjoining the Board's unlawful closure of ACRX. The question of what is best for patients potentially affected by granting or denying an injunction is given significant weight in the Court's decision to grant or deny relief. *Hopkins v. Jegley*, 267 F. Supp. 3d 1024, 1096 (E.D. Ark. 2017) (evaluating patients' interests in balancing harms and discerning public interest in evaluating request for preliminary injunction). Here, where patients are not party to this action but nonetheless affected by the Court's decision, their interest weighs in favor of granting the Plaintiffs' motion and ending the unwarranted closure of ACRX. Each day that ACRX remains closed, patients face difficulty in receiving, or are unable to receive, necessary and even life-saving medication.

Moreover, since December 2018, ACRX and Igbinovia have operated under scrutiny from the FDA and DEA. Igbinovia Decl. ¶ 2. Yet, at the end of the FDA's observation of Plaintiffs, the FDA took no adverse action with respect to the Plaintiffs, their business operation, or any of their lawfully compounded pharmaceuticals.[23] *Id.* Likewise, the DEA never instituted any suspension or revocation proceedings against the Plaintiffs, which it would have done had there been any public danger. *See* 29 C.F.R. § 1301.36(e). Igbinovia Decl ¶ 11. And, here the Board has not noticed Plaintiffs for any wrongdoing or danger to the public.

Finally, As discussed above, the Plaintiffs' loss of their entire business is an illustrative and widely accepted example of irreparable harm. The Board's actions underpinning this loss arose only due to the Board's refusal to act within its statutory and regulatory mandate.

Plaintiffs seek nothing more for the Board to follow Nevada law, and this Court's injunction requiring the Board to do so will impose no new burden upon it. Absent injunctive relief, the Plaintiffs must suffer the complete and utter loss of their business to accommodate the Board's disregard of their due process rights. It is inequitable for ACRX to remain shuttered while Plaintiffs lose the business they have created in order to indulge the Board's appetite for

[23] To the extent the FDA identified any issues for which it sought correction, it did so without imposing any kind of fine, penalty, or sanction upon ACRX. Plaintiffs eagerly complied with the FDA's requests, and confirmed in writing that they had done so.

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expedience (and at the expense of its legal obligations). This factor weighs decisively in favor of the Court granting this Motion and allowing Plaintiffs to re-open ACRX.

C. Any Bond Requirement as a Condition of Injunctive Relief Should be Minimal.

Plaintiffs seek only to preserve the status quo prior to the Board's violation of their rights, and thus the bond required by the Court should be minimal. Although a bond is required under NRCP 65(c), the purpose of the Plaintiffs' requested relief is to bind the Board to its statutory directives and require it to act within its authority provided under NRS Chapter 639 and NAC Chapter 639. Absent any evidence of harm to the public or the integrity of the practice of pharmacy within the State of Nevada, the Board stands to lose nothing by abiding by its own rules and allowing Plaintiffs to conduct their lawful business. Plaintiffs respectfully suggest that the required bond not exceed $500.00.

IV. CONCLUSION

Based on the foregoing, Plaintiffs request that the Court grant the Motion, enter a Temporary Restraining Order in their favor, and enter an order setting a hearing regarding the Temporary Restraining Order's maturation into a Preliminary Injunction. Plaintiffs have submitted a proposed Order for this purpose as Exhibit 13. Following this subsequent hearing, Plaintiffs ask that the Court enter a Preliminary Injunction enjoining the Board's conduct described in this Motion, prohibiting the further closure of ACRX, and restoring the Plaintiffs' rights to engage in their business.

DATED this 22nd day of July, 2019

HOLLAND & HART LLP

/s/ Constance L. Akridge

Constance L. Akridge
J. Malcolm DeVoy
Brittany L. Walker
9555 Hillwood Drive, 2nd Floor
Las Vegas, NV 89134

Attorneys for Plaintiffs

HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
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jmdevoy@hollandhart.com
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Attorneys for Plaintiffs

DISTRICT COURT

CLARK COUNTY, NEVADA

ACRX SPECIALTY PHARMACY, INC. a Nevada corporation; and EGHOMWARE IGBINOVIA, a/k/a JERRY IGBINOVIA, an individual,

Plaintiff,

v.

NEVADA STATE BOARD OF PHARMACY; DOES I-X; and ROE CORPORATIONS XI-XX,

Defendant.

Case No. A-19-798928-C
Dept. No. 2

DECLARATION OF EGHOMWARE IGBINOVIA IN SUPPORT OF EX PARTE MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
LAS VEGAS, NV 89134

I, Eghomware Igbinovia, also known as Jerry Igbinovia, state as follows:

1. I am a plaintiff in this action, a citizen and resident of Clark County, Nevada, and a licensed pharmacist in active and good standing within the State of Nevada, holding pharmacist license number 16316. Additionally, I am the sole shareholder, officer, director and managing pharmacist (and only pharmacist) of ACRX Specialty Pharmacy Inc., a Nevada corporation that operates as a compounding pharmacy and the only other plaintiff in this action; ACRX holds pharmacy license number PH03673, which is active and in good standing. On these bases, I have personal knowledge of the matters set forth within this declaration. I am over 18 years of age,

have never been convicted of any felony, and am competent to testify about the matters contained in this declaration if called to do so at trial.

2. Beginning in 2018, I believe I have been the subject of harassment and unreasonable amounts of attention by the Nevada State Board of Pharmacy (the "Board"). Since January 1, 2019, ACRX and I have been subject to investigations and inquiries from the Food and Drug Administration ("FDA")[1] and Drug Enforcement Administration ("DEA"); I believe that the Board complained to both the FDA and DEA about me, and sought to enlist these administrations to investigate myself and my pharmacy in an effort to close ACRX and stop my business.

3. Neither the FDA nor the DEA ordered the closure of ACRX, or ordered me to cease my practice as a licensed pharmacist.

4. On June 20, 2019, I was arrested by federal law enforcement officials charging me with violations of 21 U.S.C. §§ 841(a)(1), (b)(1)(E), (b)(1)(E)(i), and 846 for allegedly distributing and being involved in a conspiracy to distribute buprenorphine, a Schedule III controlled substance. That same day the federal law enforcement officials who arrested me also removed a number of computers from ACRX. I was in custody for only hours and was released that same day (June 20, 2019) on my own recognizance without posting a bond.

5. On June 20, 2019, the Board locked me and other ACRX employees out of the pharmacy because no pharmacist would be present to account for the pharmacy's supply of controlled substances. At around 5:00 p.m. on June 20, 2019, a Board representative told my wife that my license as a pharmacist had not been suspended, but the Board needed to close the pharmacy because no pharmacist was available to supervise its supply of controlled substances.

6. During the government's June 20, 2019 seizure of computers from ACRX, one Board representative told an ACRX employee that the pharmacy was shut down, and that the employee should find a new job. Additionally, that same day, the Board called the agents for ACRX's landlord, advising them that ACRX had been raided by law enforcement officers, the Board had shut down the pharmacy, and that I was in custody. I am unaware how the Board

[1] The FDA's multi-week inspection of ACRX was performed jointly with the Board.

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learned the identity of ACRX's landlord in order to initiate contact with its agents and make these statements about me.

7. On June 21, 2019, I informed the Board through my counsel that I was no longer under arrest. The Board informed me that the pharmacy could not operate without its computers, and I informed the Board that I maintained an archival copy of all the data that was on the computers taken from ACRX.

8. I was then, and am now, ready, willing, and capable of restoring all of the data found on the computers removed from ACRX on June 20, 2019.

9. Although I informed the Board on June 21, 2019 that I was no longer under arrest and was free to continue my work at ACRX, and that I could restore all of the data and information that was found on the computers removed from ACRX on June 20, the Board has refused to allow me to access ACRX for any reason. Because of the continuous attention and upkeep required for ACRX's operation, including its sterile compounding facilities, I am concerned that the Board's indefinite closure of ACRX could cause long-term and even permanent damage to its facilities, patient and wholesaler relationships, relationships with employees, and the business generally.

10. I have never agreed to keep ACRX closed for any duration of time. Moreover, I have never represented to my counsel that I agreed to keep ACRX closed, and I have never represented to the Board that I agreed to keep ACRX closed.

11. I have not received any accusation from the Board, whether as to myself or for ACRX, which is required for the Board to initiate any kind of disciplinary proceedings against myself or ACRX. Similarly, I have not received any kind of complaint, notice, demand, decision, determination, or court or administrative order, from any federal, state, or other governmental authority, that restricts, limits, conditions, or suspends any license, registration, certificate, or other legal right that I or ACRX have to conduct business in Clark County, Nevada.

//

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LAS VEGAS, NV 89134

I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED on this 22 day of July, 2019, in Clark County, Nevada.

Eghomware Igbinovia,
also known as Jerry Igbinovia

13263790_v8

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DECL
Constance L. Akridge
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jmdevoy@hollandhart.com
blwalker@hollandhart.com

Attorneys for ACRX SPECIALTY PHARMACY, INC. and EGHOMWARE IGBINOVIA, a/k/a JERRY IGBINOVIA

DISTRICT COURT

CLARK COUNTY, NEVADA

ACRX SPECIALTY PHARMACY, INC. a Nevada corporation; and EGHOMWARE IGBINOVIA, a/k/a JERRY IGBINOVIA, an individual, Plaintiff, v. NEVADA STATE BOARD OF PHARMACY; DOES I-X; and ROE CORPORATIONS XI-XX, Defendant.	Case No. A-19-798928-C Dept. No. 2 **DECLARATION OF CONSTANCE L. AKRIDGE, ESQ. IN SUPPORT OF EX PARTE MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
LAS VEGAS, NV 89134

I, Constance L. Akridge, Esq., hereby declare as follows:

1. I am a Partner of the law firm Holland & Hart, LLP, and counsel of record for the Plaintiffs in the above-captioned case. I am duly admitted to practice law in the State of Nevada. I have personal knowledge of the matters contained within this declaration and am competent to testify regarding them if called to do so at trial.

2. Plaintiffs have filed a complaint against the Nevada State Board of Pharmacy (the "Board") regarding the Board's putative involuntary closure of ACRX Specialty Pharmacy Inc ("ACRX"), and the Board's conduct that constitutes a taking of the privileges conferred upon

ACRX and Eghomware Igbinovia, a/k/a Jerry Igbinovia ("Igbinovia") without notice and hearing required under, among other authorities, NRS 233B.121 through NRS 233B.127, and NRS 639.241.

3. Plaintiffs have filed their Ex Parte Motion for Temporary Restraining Order and Preliminary Injunction in order to maintain the status quo of ACRX prior to the Board's unjustified closure of the pharmacy adequate legal grounds to do so.

4. The Board closed ACRX on June 20, 2019, when federal law enforcement agencies seized nine (9) computers from ACRX and arrested Igbinovia. Despite these events, Igbinovia was processed and released from custody on his own recognizance that very same day, without the requirement to post any bond.

5. Since June 21, 2019, Igbinovia, whether individually or through counsel, has been in near-constant contact with the Board attempting to re-open ACRX, so that they could resume their pharmacy activities.

6. During my conversations with the Board's General Counsel, Paul Edwards, I have learned that the Board has not filed any accusations against either of the Plaintiffs. Under NRS 639.241(1), the filing of an accusation is a necessary first step to initiating any hearing or proceeding to revoke, suspend, limit, or condition any license issued by the Board.

7. The Plaintiffs hold active licenses as a pharmacy and pharmacist, respectively, issued by the Board.

8. A true and correct copy of the Board's online license verification tool, showing that ACRX maintained an active pharmacy license as of July 18, 2019, is attached hereto as **Exhibit 1**.

9. A true and correct copy of the Nevada Secretary of State's publicly available information for ACRX, obtained through the Nevada Secretary of State's website found at www.nvsos.gov, is attached hereto as **Exhibit 2**.

10. A true and correct copy of the Board's online license verification tool, showing that Igbinovia maintained an active pharmacy license as of July 18, 2019, is attached hereto as **Exhibit 3**.

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11. To the best of my knowledge and based on my research, no action has been instituted by any governmental authority against either of the Plaintiffs seeking (let alone obtaining) any closure of ACRX or limitation of their right and ability to operate their pharmacy business.

12. Similarly, to the best of my knowledge and based on my research, no state or federal governmental entity has instituted any administrative or other proceeding against either of the Plaintiffs seeking any closure of ACRX or any restriction, limitation, suspension, or revocation of any license, registration, certificate, or credential held by either of the Plaintiffs. No order, injunction, finding, or other ruling or determination that could limit Plaintiffs' operation of ACRX currently exists.

13. On June 20, 2019, a law enforcement raid on ACRX led to Igbinovia's arrest and the seizure of nine (9) computers from ACRX. Igbinovia was released from custody on his own recognizance that same day and possesses a complete backup of all data found on those computers that he can re-install on new computers and restore to the same condition as those seized from ACRX.

14. A true and correct copy of the Board's Office of the General Counsel's Notice of Involuntary Closure of Pharmacy and Right to Hearing ("Notice of Involuntary Closure"), issued on June 21, 2019, is attached hereto as **Exhibit 4**.

15. Plaintiffs corrected the only two bases the Board identified for its closure by June 21, 2019, and informed the Board of this fact; nonetheless, the Board has refused to rescind its putative "involuntary closure" of ACRX.

16. Following the Board's Notice of Involuntary Closure, the Board's General Counsel began negotiations with Plaintiffs' counsel regarding the re-opening of ACRX, and potential conditions to be placed upon Igbinovia in exchange for re-opening the pharmacy.

17. The Board set a hearing for July 18, 2019 regarding the Notice of Involuntary Closure, of which it notified ACRX on July 3, 2019.

18. A true and correct copy of the Board's July 3, 2019 correspondence regarding the July 18, 2019 hearing to be held on ACRX's involuntary closure is attached hereto as **Exhibit 5**.

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19. Despite not filing any accusation against ACRX, the Board purported to send notice of its July 18, 2019 hearing regarding the Notice of Involuntary Closure to ACRX in the form of its July 11, 2019 Statement to the Respondent and Notice of Hearing.

20. A true and correct copy of the Board's Statement to the Respondent and Notice of Hearing, issued to ACRX on July 11, 2019, is attached hereto as **Exhibit 6**.

21. From June 21, 2019 through the time my firm was retained as counsel shortly before July 18, 2019, Plaintiffs' counsel and the Board engaged in discussions about the potential re-opening of ACRX.

22. Initially, the Board proposed that Igbinovia suspend his DEA Registration, as the DEA had taken no action to suspend or revoke his registration. The Board recognized that doing so may adversely affect Igbinovia's pharmacist license, but proposed that ACRX may be allowed to re-open if Igbinovia suspended his ability to dispense controlled substances, and that the Board would seek to have a concomitant suspension of Igbinovia license due to surrendering his DEA Registration stayed in satisfaction of NRS 639.2107.

23. A true and correct copy of the July 2, 2019 e-mail chain between Paul Edwards and Matthew Dushoff, Esq., is attached hereto as **Exhibit 7**.

24. Suddenly, around July 10, 2019, Igbinovia's suspension of his DEA Registration no longer was sufficient as a condition of ACRX's re-opening: the Board demanded that Igbinovia refrain from compounding, as defined within NAC 639.6625, as well. As ACRX is a compounding pharmacy, prohibiting its sole pharmacist from compounding would be the functional equivalent to remaining closed.

25. A true and correct copy of the July 11, 2019 e-mail chain between Paul Edwards and Matthew Dushoff, Esq., is attached hereto as **Exhibit 8**.

26. The Board conceded during these negotiations that it had not filed accusations against the Plaintiffs. While Board General Counsel Paul Edwards represented that the accusations were forthcoming, he refused to discuss the particular facts, circumstances, allegedly violated statutes or rules, or other matters asserted in the accusations that would justify ACRX's continued closure.

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27. Additionally, during ACRX's closure, Plaintiffs received dozens if not hundreds of calls from patients regarding the status of their prescriptions. Plaintiffs' counsel notified the Board of these concerns, and the public safety issues inherent within them.

28. A true and correct copy of the July 2, 2019 e-mail chain between Paul Edwards and Matthew Dushoff, Esq., regarding calls from patients to ACRX pertaining to their prescriptions, is attached hereto as **Exhibit 9**.

29. Only July 17, 2019, I was able to speak with the Board's General Counsel, Paul Edwards, regarding Plaintiffs and seeking to reach a resolution by which the Board's Notice of Involuntary Closure would be rescinded and ACRX would be allowed to re-open.

30. On behalf of the Plaintiffs, I asked the Board's General Counsel for a continuance of the July 18, 2019 hearing since the Board failed to give adequate notice to Plaintiffs of the specific violations of Nevada law justifying the involuntary closure of ACRX, and a hearing would be futile due to the Board's lack of specificity as to what conduct and legal authorities would be at issue.

31. Additionally, during my discussions with the Board's General Counsel, I was informed that ACRX would not be re-opened without significant business-terminating restrictions (i.e. no sales of controlled substances and no compounding), and Plaintiffs would not be permitted to resume their lawful activities pursuant to their respective licenses, even if the July 18, 2019 hearing went forward. It was apparent to me that the Board had pre-determined the outcome of this hearing, in addition to the other deficiencies regarding how it was noticed, and was scheduled long after the Board's actions.

32. On July 18, 2019, I transmitted Mr. Edwards a demand that the Board immediately rescind its Notice of Involuntary Closure and allow Plaintiffs to re-open ACRX.

33. A true and correct copy of the July 18, 2019 correspondence is attached hereto as **Exhibit 10**.

34. On July 19, 2018, I received a letter from the Board claiming that "ACRX remains closed based on a stipulated agreement between Board Staff and your client." This is false. Neither myself nor my client ever agreed to keep ACRX closed.

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LAS VEGAS, NV 89134

35. A true and correct copy of the July 19, 2019 correspondence is attached hereto as **Exhibit 11**.

I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED on this 22nd day of July, 2019 in Clark County, Nevada.

Constance L. Akridge, Esq.

13263439_v5

HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
LAS VEGAS, NV 89134

EXHIBIT 1

EXHIBIT 1

Nevada State Board of Pharmacy

Online reporting of disciplinary action is currently being updated. For current information on disciplinary actions taken against licensees please contact Board Staff at shunting@pharmacy.nv.gov (mailto:shunting@pharmacy.nv.gov) or (775) 850-1440.

VERIFY LICENSE

Facility Name	License Number#	City	State	Country	Discipline	Action
ACRX SPECIALTY PHARMACY	PH03673	LAS VEGAS	NV	United States	None	

License Number : PH03673
Name : ACRX SPECIALTY PHARMACY
License Type : Pharmacy
License Status : Active
License Date : 01/04/2017
Discipline :
Expiration Date : 10/31/2020

EXHIBIT 2

EXHIBIT 2

ACRX SPECIALTY PHARMACY INC

Q New Search Manage this Business $ Calculate List Fees Printer Friendly

Business Entity Information			
Status:	Active	File Date:	9/18/2015
Type:	Domestic Corporation	Entity Number:	E0445312015-5
Qualifying State:	NV	List of Officers Due:	9/30/2019
Managed By:		Expiration Date:	
NV Business ID:	NV20151559249	Business License Exp:	9/30/2019

Additional Information	
Central Index Key:	
Benefit Corporation:	YES

Registered Agent Information			
Name:	OMO USIGBE TAX SERVICE	Address 1:	3085 EAST RUSSELL RD STE B
Address 2:		City:	LAS VEGAS
State:	NV	Zip Code:	89120
Phone:		Fax:	
Mailing Address 1:		Mailing Address 2:	
Mailing City:		Mailing State:	NV
Mailing Zip Code:			
Agent Type:	Commercial Registered Agent - Corporation		
Jurisdiction:	CLARK COUNTY	Status:	Active

View all business entities under this registered agent

Financial Information			
No Par Share Count:	0	Capital Amount:	$ 20,000.00
Par Share Count:	200.00	Par Share Value:	$ 100.00

- Officers ☐ Include Inactive Officers

President - EGHOMWARE IGBINOVIA			
Address 1:	7568 MOSSBACK STREET	Address 2:	
City:	LAS VEGAS	State:	NV
Zip Code:	89123	Country:	
Status:	Active	Email:	

Secretary - EGHOMWARE IGBINOVIA			
Address 1:	7568 MOSSBACK STREET	Address 2:	
City:	LAS VEGAS	State:	NV
Zip Code:	89123	Country:	
Status:	Active	Email:	

Treasurer - EGHOMWARE IGBINOVIA			
Address 1:	7568 MOSSBACK STREET	Address 2:	
City:	LAS VEGAS	State:	NV
Zip Code:	89123	Country:	
Status:	Active	Email:	

Director - EGHOMWARE IGBINOVIA			
Address 1:	7568 MOSSBACK STREET	Address 2:	
City:	LAS VEGAS	State:	NV
Zip Code:	89123	Country:	
Status:	Active	Email:	

− Actions\Amendments

Click here to view 5 actions\amendments associated with this company

EXHIBIT 3

EXHIBIT 3

Nevada State Board of Pharmacy

Online reporting of disciplinary action is currently being updated. For current information on disciplinary actions taken against licensees please contact Board Staff at shunting@pharmacy.nv.gov (mailto:shunting@pharmacy.nv.gov) or (775) 850-1440.

VERIFY LICENSE

Last Name	First Name	License#	City	State	Country	Discipline	Action
Igbinovia	Eghe	16316	LAS VEGAS	NV	United States	None	

License Number : 16316
Name : Igbinovia, Eghe
License Type : Pharmacist
License Status : Active
License Date : 02/19/2004
Discipline :
Expiration Date : 10/31/2019

EXHIBIT 4

EXHIBIT 4

NEVADA STATE BOARD OF PHARMACY
OFFICE OF THE GENERAL COUNSEL
WRITER'S DIRECT DIAL: (775) 850-1440 • E-MAIL: bkandt@pharmacy.nv.gov • FAX: (775) 850-1444

June 21, 2019

VIA U.S. MAIL and EMAIL TO mdushoff@klnevada.com

Matthew T. Dushoff, Esq.
Kolesar & Leatham, Chtd.
400 South Rampart Blvd., Suite 400
Las Vegas, NV 89145

Re: Notice of Involuntary Closure of Pharmacy and Right to Hearing - ACRX Specialty Pharmacy, Certificate of Registration No. PH03673

Dear Mr. Dushoff:

This will confirm that Nevada State Board of Pharmacy (Board) has taken necessary action pursuant to NAC 639.570 to effectuate an involuntary closure of your client Jerry Igbinovia's pharmacy, ACRX Specialty Pharmacy, located at 3200 Soaring Gulls Drive, Suite #101 Las Vegas, NV 89129. That involuntary closure was necessary after federal law enforcement agents arrested your client and seized ACRX Specialty Pharmacy's computer system on June 20, 2019, rendering the pharmacy unable to operate in conformance with applicable law.

Pursuant to NRS 233B.121, your client may request a hearing before the Board to contest ACRX Specialty Pharmacy's involuntary closure by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Please be aware that the forgoing does not preclude a formal investigation, summary suspension pursuant to NRS 233B.127(3), or filing of an accusation pursuant to NRS 639.241. If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

EXHIBIT 5

EXHIBIT 5

Nevada State Board of Pharmacy

985 DAMONTE RANCH PARKWAY • SUITE 206 • RENO, NEVADA 89521
(775) 850-1440 • 1-800-364-2061 • FAX (775) 850-1444
E-mail: pharmacy@pharmacy.nv.gov • Website: bop.nv.gov

July 3, 2019

Matthew T. Dushoff, Esq.
Kolesar & Leatham, Chtd.
400 S Rampart Blvd #400
Las Vegas, NV 89145

Dear Sir or Madam:

The hearing pursuant to NRS 233B.121 to contest ACRX Specialty Pharmacy's involuntary closure pursuant to NAC 639.570 for case number 19-044-PH-S has been scheduled for the following:

Thursday, July 18, 2019
1:30 pm or soon thereafter
Hilton Garden Inn
7830 S Las Vegas Blvd
Las Vegas, Nevada

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact us.

Sincerely,

Candy M Nally

Candy M. Nally
Licensing Specialist

EXHIBIT 6

EXHIBIT 6

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-044-PH-S**
	)	
Petitioner,	)	
v.	)	**STATEMENT TO THE**
	)	**RESPONDENT AND**
ACRX SPECIALTY PHARMACY,	)	**NOTICE OF HEARING**
Certificate of Registration No. PH03673,	)	
	)	
Respondent.	/	

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

I.

On or about June 20, 2019, agents from the Drug Enforcement Administration (DEA) arrested ACRX Specialty Pharmacy (ACRX) owner Eghomware Igbinovia, a/k/a Jerry Igbinovia (Mr. Igbinovia), and seized ACRX's computer system. With the arrest of Mr. Igbinovia, the sole owner, operator, managing pharmacist/pharmacist in charge and only full-time pharmacist on staff at ACRX, the pharmacy was left unable to operate in conformance with applicable law.

II.

As a result of that arrest and seizure, and pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NAC 639.570, Board Staff served ACRX with a Notice of Involuntary Closure of Pharmacy and Right to Hearing on June 21, 2019.

III.

An involuntary closure includes "[c]losure as a result of action by the Federal Government, the State of Nevada or the governing body of any county or city within the State of Nevada." NAC 639.570(5)(a).

IV.

You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121. This statement shall serve as notice of ACRX's right to a hearing to contest the

involuntary closure of the pharmacy pursuant to NAC 639.570. During the hearing, ACRX will have the opportunity to show the Board that the pharmacy is now able to operate in compliance with Nevada law. If ACRX fails to appear at the hearing and the Board finds that it was given sufficient legal notice of the hearing, the Board may accept the allegations above as true and may proceed to consider the case and render a decision.

V.

The Board has scheduled the hearing on this matter for Thursday, July 18, 2019, at 1:30 p.m. or soon thereafter. The hearing will occur at the at the Hilton Garden Inn located at 7830 South Las Vegas Blvd., Las Vegas, Nevada.

VI.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

DATED this 11 day of July, 2019.

Yenh Long, Pharm.D., Deputy Executive Secretary
of the Nevada State Board of Pharmacy, on behalf
of J. David Wuest, R.Ph. Executive Secretary

EXHIBIT 7

EXHIBIT 7

Jay DeVoy

From: Paul Edwards <pedwards@pharmacy.nv.gov>
Sent: Tuesday, July 2, 2019 5:05 PM
To: Matthew T. Dushoff
Cc: Russ Marsh; Richard A.. Wright; Michael D. Davidson; DRosen@foley.com; Kristina R. Cole; David Wuest; Yenh Long; Brett Kandt
Subject: RE: ACRX

Matt,

Thanks for sending the draft. I will review it and make recommendations to Board Staff regarding its terms.

I would need a fully executed copy before we can act, but I think you and I are saying about the same thing. If the operation of the statute (NRS 639.2107) forces the suspension of ACRX's license, I believe we can stay that suspension until the matter is presented to the Board for further determination. That will occur at the July 2019 Board Meeting. The Board will then have to decide how it wants to proceed.

Best regards,

S. Paul Edwards, Esq.
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89509
(775) 850-1440 (phone)
(775) 850-1444 (fax)
E-mail: pedwards@pharmacy.nv.gov
Web page: bop.nv.gov

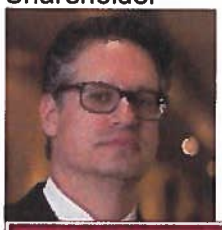
From: Matthew T. Dushoff <mdushoff@klnevada.com>
Sent: Tuesday, July 2, 2019 4:53 PM
To: Paul Edwards <pedwards@pharmacy.nv.gov>
Cc: Russ Marsh <russ@wmllawlv.com>; Richard A.. Wright <rick@wmllawlv.com>; Michael D. Davidson <mdavidson@klnevada.com>; DRosen@foley.com; Kristina R. Cole <kcole@klnevada.com>; David Wuest <dwuest@pharmacy.nv.gov>; Yenh Long <ylong@pharmacy.nv.gov>; Brett Kandt <bkandt@pharmacy.nv.gov>
Subject: RE: ACRX

Paul,

Attached is the draft of the DEA Agreement that we will execute. ACRX will have its DEA Registration suspended pending the outcome of the federal case. We are being put in a Catch-22 position. We are aware of the statute. During one of our conversations, it was made clear to us that Staff did not oppose the staying of the suspension pending the outcome of the federal case. Do we still have Staff's support on that position? Will Staff make that recommendation to the Board? Thank you.

Matthew T. Dushoff, Esq.

Shareholder



KOLESAR & LEATHAM

ATTORNEYS AT LAW

Office: 702.362.7800 Cell: 702.279.8875
Web: www.klnevada.com Bio: Attorney Bio
400 S. Rampart Blvd. | Suite 400 | Las Vegas | NV 89145

From: Paul Edwards [mailto:pedwards@pharmacy.nv.gov]
Sent: Tuesday, July 02, 2019 4:29 PM
To: Matthew T. Dushoff <mdushoff@klnevada.com>
Cc: Russ Marsh <russ@wmllawlv.com>; Richard A.. Wright <rick@wmllawlv.com>; Michael D. Davidson <mdavidson@klnevada.com>; DRosen@foley.com; Kristina R. Cole <kcole@klnevada.com>; David Wuest <dwuest@pharmacy.nv.gov>; Yenh Long <ylong@pharmacy.nv.gov>; Brett Kandt <bkandt@pharmacy.nv.gov>
Subject: RE: ACRX

Matt,

Can you send me a fully executed copy of the agreement with DEA for Board Staff's review? We cannot go forward without knowing the terms of that agreement.

Also, you need to be aware of NRS 639.2107.

NRS 639.2107 Surrender, revocation or suspension by licensing board or Drug Enforcement Administration: Immediate suspension of certificate, license or registration. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, 454.00958 or 639.0125, by a licensing board or the

Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to this chapter or chapter 453 or 454 of NRS to possess, administer, prescribe or dispense drugs.

In light of that statute, Board Staff cannot give any assurance that it will not suspend the pharmacy's license or the pharmacist's registration. The statutes mandates suspension, but we have discussed the possibility of suspending, then staying that suspension until the matter goes before the Board in July for further determination.

Best regards,

S. Paul Edwards, Esq.
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89509
(775) 850-1440 (phone)
(775) 850-1444 (fax)
E-mail: pedwards@pharmacy.nv.gov
Web page: bop.nv.gov

From: Matthew T. Dushoff <mdushoff@klnevada.com>
Sent: Tuesday, July 2, 2019 2:25 PM
To: Paul Edwards <pedwards@pharmacy.nv.gov>
Cc: Russ Marsh <russ@wmllawlv.com>; Richard A.. Wright <rick@wmllawlv.com>; Michael D. Davidson <mdavidson@klnevada.com>; DRosen@foley.com; Kristina R. Cole <kcole@klnevada.com>
Subject: ACRX

Paul,

I left you a message on your work phone. We have an agreement with the DEA that will temporarily suspend ACRX's DEA Registration pending the outcome of the federal case. I just need assurances in writing that the State Board will not suspend ACRX due to the DEA suspension and that the Board will allow ACRX to reopen (with the obvious caveat that ACRX cannot work with controlled substances) pending the outcome of the federal matter. We would like to get this done this week so we can have ACRX open as soon as possible. To that end, we also need a date for the Board to come in and inventory the controlled substances. Thank you.

Matthew T. Dushoff, Esq.

Shareholder

KOLESAR & LEATHAM
ATTORNEYS AT LAW

Office: 702.362.7800 Cell: 702.279.8875
Web: www.klnevada.com Bio: Attorney Bio
400 S. Rampart Blvd. | Suite 400 | Las Vegas | NV 89145

This message was secured by Zix®.

EXHIBIT 8

EXHIBIT 8

Jay DeVoy

From: Paul Edwards <pedwards@pharmacy.nv.gov>
Sent: Thursday, July 11, 2019 7:56 AM
To: Matthew T. Dushoff
Cc: Brett Kandt; David Wuest; Yenh Long
Subject: RE: ACRx

Matt,

That is essentially correct. I have will attempt to more fully articulate the points of the offer below:

1. ACRX would voluntarily surrender its DEA registration pending the outcome of the open federal case. (Per the draft agreement you provided from DOJ.)
2. State would work with ACRX to secure/remove its inventory of CS from the pharmacy.
3. State would then suspend ACRX's pharmacy license per NRS 639.2107 (due to surrender of DEA), but stay that suspension.
4. State would allow ACRX to reopen on a restricted basis, to dispense only commercially available dangerous drugs. (ACRX could not dispense controlled substances because it surrendered its DEA, and it would agree not to compounded or dispense any compounded medications (sterile and non-sterile). That includes a prohibition on dispensing the compounded medications it already made and that are ready to dispense.
5. With such an agreement in place, I believe the July 18 hearing would be moot, and could be vacated.
6. Board Staff anticipates that it will file Accusations in the open state investigations in late July/early August regarding the compounding issues. The intent is to have those matters on the agenda for hearing at the Board's September 4-5, 2019 Board Meeting in Reno. By way of an Order, the Board (Memebers) would set the terms under which ACRX could resume compounding, i.e., correct faulty/unsafe procedures, documentation, reinspection of factility, etc. So long as ACRX complies with the Order, it could start compounding again.

If ACRX will agree to those essential terms, I will work them into a formal agreement for signatures. Contact me if you have questions.

Best regards,

S. Paul Edwards, Esq.
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89509
(775) 850-1440 (phone)
(775) 850-1444 (fax)
E-mail: pedwards@pharmacy.nv.gov
Web page: bop.nv.gov

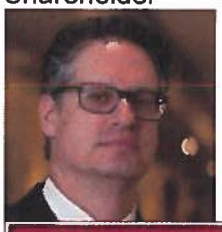
From: Matthew T. Dushoff <mdushoff@klnevada.com>
Sent: Wednesday, July 10, 2019 6:28 PM
To: Paul Edwards <pedwards@pharmacy.nv.gov>
Cc: Kristina R. Cole <kcole@klnevada.com>; Michael D. Davidson <mdavidson@klnevada.com>; Russ Marsh <russ@wmllawlv.com>; Richard A.. Wright <rick@wmllawlv.com>; DRosen@foley.com
Subject: ACRx

Paul,

This correspondence is to confirm our conversation this afternoon. As we previously discussed, the offer from the State was that ARCx stipulate to a voluntary surrender of their DEA Registration, the State would stay the suspension of the license (caused by the voluntary surrender of the DEA Registration), and then ACRx can re-open with no controlled substances pending the outcome of the federal case and/or the decision from the Board. Today, you informed me that there are 2 active investigations against ACRx that cause the State concern regarding allowing Jerry to continue to compound even non-controlled substances. As such, the State's offer has changed to: ACRx stipulates to a voluntary surrender of their DEA Registration, the State would stay the suspension of the license and allow ACRx to reopen, but Jerry cannot compound any drugs (even non-controlled substances). Please confirm that this is what the offer was and is from the State. I want to make sure that I provide my client an accurate statement regarding the offer. Thank you very much.

Matthew T. Dushoff, Esq.

Shareholder



KOLESAR & LEATHAM
ATTORNEYS AT LAW

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Web: www.klnevada.com Bio: Attorney Bio
400 S. Rampart Blvd. | Suite 400 | Las Vegas | NV 89145

EXHIBIT 9

EXHIBIT 9

Jay DeVoy

From: Paul Edwards <pedwards@pharmacy.nv.gov>
Sent: Tuesday, July 2, 2019 4:34 PM
To: Matthew T. Dushoff
Cc: David Wuest; Yenh Long; Brett Kandt
Subject: RE: ACRX

Matt,

I don't believe that the timeline you propose is feasible. Board Staff needs to receive and review the DEA temporary suspension agreement. If it is acceptable, we then need to schedule a time for Board Staff to inventory and secure the controlled substances. I have no idea our Las Vegas staff's schedules look like this week, but I suspect they are complicated with time off and the upcoming holiday.

Best regards,

S. Paul Edwards, Esq.
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89509
(775) 850-1440 (phone)
(775) 850-1444 (fax)
E-mail: pedwards@pharmacy.nv.gov
Web page: bop.nv.gov

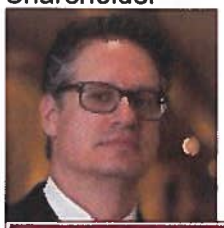
From: Matthew T. Dushoff <mdushoff@klnevada.com>
Sent: Tuesday, July 2, 2019 4:09 PM
To: Paul Edwards <pedwards@pharmacy.nv.gov>
Cc: Russ Marsh <russ@wmllawlv.com>; Richard A.. Wright <rick@wmllawlv.com>; DRosen@foley.com; Michael D. Davidson <mdavidson@klnevada.com>; Brett Kandt <bkandt@pharmacy.nv.gov>; Kristina R. Cole <kcole@klnevada.com>
Subject: ACRX

Paul,

I just received a call from my client regarding the State's response to reopening. They have been getting calls from their patients regarding prescriptions and they need to get open as soon as possible. I would like to get this done tomorrow, so they can be open. Thank you.

Matthew T. Dushoff, Esq.

Shareholder



KOLESAR & LEATHAM

ATTORNEYS AT LAW

Office: 702.362.7800 Cell: 702.279.8875
Web: www.klnevada.com Bio: Attorney Bio
400 S. Rampart Blvd. | Suite 400 | Las Vegas | NV 89145

EXHIBIT 10

EXHIBIT 10

HOLLAND&HART

Constance Akridge
Partner
Phone (702) 222-2543
Fax (702) 475-5736
clakridge@hollandhart.com

July 18, 2019

VIA E-MAIL AND U.S. MAIL

Paul Edwards
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: Eghomware Igbinovia, a/k/a Jerry Igbinovia (Certificate of Registration No. 16316)
ACRX Specialty Pharmacy Inc. (Certificate of Registration No. PH03673)

Dear Mr. Edwards:

I am writing to inform you that J. Malcolm DeVoy, Brittany Walker, and myself have been retained to represent Mr. Igbinovia and ACRX Specialty Pharmacy Inc. ("the Pharmacy") in place and instead of their former counsel, Matthew T. Dushoff and Michael Davidson of Kolesar & Leatham, Chtd. We have only just now received the file from Mr. Igbinovia and the Pharmacy's prior counsel.

On June 20, 2019, Drug Enforcement Administration ("DEA") agents arrested Mr. Igbinovia and seized the Pharmacy's nine (9) computer systems, and that same day, the Nevada State Board of Pharmacy (the "Board") closed the Pharmacy stating that no pharmacist was on duty to lock the Pharmacy. However, if the Board had provided notice of the impending closure, Mr. Igbinovia would have procured a pharmacist to lock the Pharmacy. The Board also informed Mr. Igbinovia's employee that when Mr. Igbinovia was released the Board would reopen the Pharmacy. On June 21, 2019, Mr. Igbinovia called the Board to reopen the Pharmacy, but his requests were ignored.

On Monday, June 24, 2019, Mr. Igbinovia received a notice of involuntary closure, conflating him with the Pharmacy, and stating that as a result of the DEA's actions the Pharmacy was unable to "operate in conformance with applicable law." This notice did not specify what "applicable law" with which the Pharmacy was unable to comply or of any underlying statutory violations committed by the Pharmacy. Accordingly, the State Board of Pharmacy wrongfully closed the Pharmacy without cause, and without complying with NRS 233B.121(b) (requiring the notice to include the particular sections of the statutes and regulations upon which the Board's action is based).

HOLLAND&HART LLP

Moreover, the Board has not filed an Accusation against Mr. Igbnivoia or the Pharmacy or otherwise initiated proceedings seeking summary suspension of their licenses or obtained suspension of their respective licenses, and the federal government has not taken any action close the Pharmacy under 21 USC 824.

Mr. Igbinovia is a duly licensed pharmacist by the state of Nevada and is in good standing with no disciplinary actions against him. As you were informed by Mr. Dushoff on June 20, 2019, Mr. Igbinovia was in government custody for less than eight (8) hours and has not been in government custody since June 20, 2019. You were further informed by Mr. Dushoff on June 21, 2019 that Mr. Igbinovia has retained and has access to a full, complete, and secure backup of all data seized from the Pharmacy on June 20, 2019. Mr. Igbinovia is capable of reinstalling this data on a new computer to be used in the Pharmacy's operations. Mr. Igbinovia is fully capable of reopening his Pharmacy and doing business. There is no lawful cause for the Pharmacy's continued closure.

We hereby demand that the State Board of Pharmacy immediately rescind the involuntary closure of the Pharmacy.

Thank you for your attention to this matter.

Sincerely,

Constance L. Akridge

Constance Akridge
Partner
of Holland & Hart LLP

CA:BLW

cc:

EXHIBIT 11

EXHIBIT 11

NEVADA STATE BOARD OF PHARMACY
OFFICE OF THE GENERAL COUNSEL
WRITER'S DIRECT DIAL: (775) 850-1440 • E-MAIL: pedwardst@pharmacy.nv.gov • FAX: (775) 850-1444

July 19, 2019

VIA ELECTRONIC MAIL AND U.S. MAIL
Constance Akridge
Holland & Hart
9555 Hillwood Drive, 2nd Floor
Las Vegas, NV 89134-0532

Re: ACRX Specialty Pharmacy Inc. (Certificate of Registration No. PH03673)

Dear Ms. Akridge:

I am writing in response to your letter dated July 18, 2019, in the above referenced matter. In that letter, you demand that the Nevada State Board of Pharmacy (Board) immediately rescind the involuntary closure of ACRX Specialty Pharmacy (ACRX).

As an initial matter, ACRX remains closed based on a stipulated agreement between Board Staff and your client. That agreement came about after your client, through its counsel, Mr. Dushoff, requested a hearing before the Board to contest the NAC 639.570 involuntary closure of ACRX. Board Staff honored that request, scheduled a hearing and properly noticed it. That hearing was set for Thursday, July 18, 2019 (yesterday).

During our discussions Mr. Dushoff never challenged the legal or factual basis for the involuntary closure, nor did he raise any objection to the adequacy of the notice the Board provided pursuant to NRS 233.121. After Board Staff scheduled the hearing, your client reversed course and asked the Board to vacate the hearing with the understanding that the involuntary closure would stay in place until the Board's next meeting on September 4-5, 2019. ACRX's stated intent in seeking a continuance was to allow it additional time to consider a separate agreement that Board Staff offered which, if accepted, would allow ACRX to reopen sooner. Board Staff therefore vacated the hearing at your client's request.

Secondly, the basis for ACRX's involuntary closure pursuant to NAC 639.570 is clear and the closure is well founded. On June 20, 2019, the date of the involuntary closure, Mr. Igbinovia was the owner and the pharmacy manager/pharmacist-in-charge of ACRX. He was also its only full-time pharmacist. On that date, federal agents arrested Mr. Igbinovia, took him into custody and seized ACRX's computer systems. Board investigators were on-site on the day of the arrest and, upon Mr. Igbinovia's removal, they observed that there was no registered pharmacist present to take control of ACRX

and secure its inventory of controlled substances and dangerous drugs. Those conditions and those actions by federal agents rendered ACRX unable to operate in compliance with Nevada law. Additionally, the Board inspectors could not legally or safely leave the pharmacy unattended. That necessitated the involuntary closure of ACRX to protect the public and to secure its drug inventory.

Finally, you demand that the Board rescind the involuntary closure without providing any evidence that ACRX has overcome the basis for the involuntary closure or that ACRX can operate in compliance with all Nevada statutes and regulations. Without evidence to back your demand, and without an inspection by Board Staff to verify that ACRX is able to operate in compliance with Nevada law, you have provided no valid basis on which to rescind the voluntary closure at this time.

If you have any questions, please do not hesitate to contact me at 775-850-1440 or pedwards@pharmacy.nv.gov.

Best regards,

S. Paul Edwards
General Counsel
Nevada State Board of Pharmacy

EXHIBIT 12

EXHIBIT 12

Jay DeVoy

[redacted]

[redacted]

[redacted]

[redacted]

From: Tricia MacKenzie <tricia@northcap.com>
Date: June 21, 2019 at 4:22:42 PM PDT
To: Esosa Ahcsr <esosai@ahcsr.com>
Cc: "admin@ahcsr.com" <admin@ahcsr.com>, "jerry@acrxpharmacy.com" <jerry@acrxpharmacy.com>
Subject: Re: ACRX Pharmacy - 3200 Soaring Gulls, Suite 101

Esosa,

I am sorry you feel my letter was threatening, as it was not intended to be so, just a reminder of the terms outlined in the Lease Agreement.

It was concerning to us when we received a call yesterday morning from the State Board of Pharmacy advising us the location had been shut down by them, the FBI and the DEA and that Jerry had been taken into custody. It would have been appropriate if someone from your side reached out yesterday or at the very latest this morning to assure us there would not be an issue while this is being settled out.

Our hope is that this matter will be resolved quickly and you will be back open very soon!

Please understand this type of situation is very concerning to the Landlord and we must make sure we are clear as to the expectations, which remain the same and unchanged.

We look forward to a quick resolution for you all and the business back open for continuous operations.

We would also appreciate you keeping us updated as to the circumstances of the business being able to re-open.

Thank you very much!

Tricia MacKenzie
Northcap Commercial
OUR OFFICE HAS MOVED!
Please note our new address:
400 South Rampart Blvd. Ste 220
Las Vegas, NV 89145
Cell: 702-666-2848

Sent from my iPhone

On Jun 21, 2019, at 3:56 PM, Esosa Ahcsr <esosai@ahcsr.com> wrote:

Tricia

I am very disappointed at the tone of this letter and the threat. Perhaps a first letter might have been an inquiry as to what the current situation is. We already mailed out the shortfall check days ago.

We haven't neglected to pay our rent in the past, nor have we indicated to you in anyway that we are unable to pay the rent at the location.

I am at a loss as to the reason for the very premature step and poor professionalism on our Landlords part!

Sent from my iPhone

On Jun 21, 2019, at 11:56 AM, Tricia MacKenzie <tricia@northcap.com> wrote:

To Whom It May Concern:

Please see the attached letter being sent out today.

Thanks,
Tricia

OUR OFFICE HAS MOVED! PLEASE NOTE OUR NEW OFFICE ADDRESS BELOW

Tricia MacKenzie
Executive Vice President
Commercial Management
O: 702.333.4455 | **C**: 702.666.2848 | **F**: 702.853.4470
400 S. Rampart Blvd. Ste 220 | Las Vegas, NV 89145
tricia@northcap.com
<image001.png>

<ACRX Letter_06.21.2019.pdf>

EXHIBIT 13

EXHIBIT 13

ORDR
Constance L. Akridge
Nevada Bar No. 3353
James M. DeVoy
Nevada Bar No. 11950
Brittany L. Walker
Nevada Bar No. 14641
HOLLAND & HART LLP
9555 Hillwood Drive, 2nd Floor
Las Vegas, NV 89134
Phone: 702.669.4600
Fax: 702.669.4650
clakridge@hollandhart.com
jmdevoy@hollandhart.com
blwalker@hollandhart.com

Attorneys for Plaintiffs

DISTRICT COURT

CLARK COUNTY, NEVADA

ACRX SPECIALTY PHARMACY, INC. a Nevada corporation; and EGHOMWARE IGBINOVIA, a/k/a JERRY IGBINOVIA, an individual,

Plaintiffs,

v.

NEVADA STATE BOARD OF PHARMACY; DOES I-X; and ROE CORPORATIONS XI-XX,

Defendant.

Case No. CaseNumber
Dept. No. Dept

[PROPOSED] ORDER GRANTING EX PARTE APPLICATION FOR TEMPORARY RESTRAINING ORDER

ORDER SETTING HEARING ON MOTION FOR PRELIMINARY INJUNCTION

Hearing Date:
Hearing Time:

HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
LAS VEGAS, NV 89134

On July 19, 2019 Plaintiffs ACRX Specialty Pharmacy Inc. ("ACRX") and Eghomware Igbinovia, a/k/a Jerry Igbinovia ("Igbinovia"), collectively the "Plaintiffs," by and through their attorneys of the law firm of Holland & Hart LLP, filed their Ex Parte Motion for Temporary Restraining Order and Preliminary Injunction on Order Shortening Time (the "Motion"), requesting immediate issuance of a temporary restraining order and a hearing on their request for a preliminary injunction.

This Court, having reviewed Plaintiffs' Motion and all attachments, the Complaint filed herein, counsel for Plaintiffs having provided copies of the Motion and Complaint to general

counsel for Defendant Nevada State Board of Pharmacy ("Board," or the "Defendant"), and good cause appearing, hereby finds that this is a proper instance for a temporary restraining order to be issued without notice because if Defendant is not restrained and enjoined by order of this Court, Plaintiffs will suffer immediate and irreparable injury through deprivation of their valid business interests and damage to their property interests in their professional licenses issued and governed by the Board. In addition to the declarations supporting the Application, pursuant to Nev. R. Civ. P. 65(b)(2), the Court preliminarily makes the following findings of fact and conclusions of law as a basis for this Order:

I. FINDINGS OF FACT

1. On June 20, 2019, the Nevada State Board of Pharmacy ("Board") involuntarily closed ACRX when law federal enforcement agencies seized nine (9) computers from ACRX and arrested Igbinovia. Despite these events, Igbinovia was processed and released from custody on his own recognizance that very same day, without the requirement to post any bond.

2. Additionally, at all times herein Igbinovia possessed a complete backup of all data found on the seized computers that he can re-install on new computers so the Board's involuntary closure based on the assumption ACRX had no access to its records was improper.

3. Once Igbinovia was released on June 20, 2019, the Board's purported basis for involuntary closure that ACRX was without a pharmacist ceased to exist.

4. Neither the Board nor any other governmental entity has obtained any order or other form of relief requiring ACRX to close, and have not instituted any proceedings for that purpose

5. As of the date of this Order, the Board has refused to re-open ACRX despite the abatement of the only reasons it provided to justify the involuntary closure of ACRX on June 20, 2019.

6. Patients who are not parties to this action have been affected by the Board's actions, and have had their access to medication disrupted by the Board's closure of ACRX; the Court finds that those affected patients' needs for prescribed, necessary, and life-saving medications is the most relevant measure of the public's interest in any injunctive relief.

///

HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
LAS VEGAS, NV 89134

II. CONCLUSIONS OF LAW

7. Plaintiffs have shown a reasonable likelihood of demonstrating likelihood of success on the merits of their claims against Defendant.

8. Plaintiffs have shown a reasonable likelihood of demonstrating they are suffering and will continue to suffer irreparable harm if this Court does not issue an injunction.

9. The public interest, including ACRX's patients who are not parties to this action, and the balance of interests between the Board and Plaintiffs, weigh in favor of this Court granting the application for a temporary restraining order.

10. The Court finds that the circumstances and conditions presented by Plaintiffs are exigent and, due to the threatened harm to Plaintiffs' business, warrants immediate and *ex parte* relief in the form of the temporary restraining order granted herein.

Accordingly, for all the foregoing reasons:

IT IS HEREBY ORDERED that a Temporary Restraining Order shall be issued restraining Defendant from further restricting Plaintiffs from operating their pharmacy.

IT IS FURTHER ORDERED that the Board is hereby ENJOINED from their continued enforcement of its putative "involuntary closure" of ACRX;

IT IS FURTHER ORDERED that the Board is hereby ENJOINED from denying Plaintiffs access to their place of business;

IT IS FURTHER ORDERED that the Board is hereby ENJOINED from prohibiting ACRX from conducting business as a licensed pharmacy;

IT IS FURTHER ORDERED that the Board is hereby ENJOINED from prohibiting Igbinovia from acting as a pharmacist; and

IT IS FURTHER ORDERED that the Board is hereby ENJOINED from prohibiting Plaintiffs from collectively operating as a pharmacy.

IT IS FUTHER ORDERED that the Board shall allow Plaintiffs to reopen their pharmacy *forthwith* and without delay, and shall take all steps necessary to restore Plaintiffs with access to ACRX's facilities immediately upon receipt of this Order.

HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
LAS VEGAS, NV 89134

IT IS FURTHER ORDERED that Plaintiffs shall file a bond for costs and damages that may be incurred by any party who may be found to be wrongfully restrained or enjoined from this Order in the total sum of $500.00.

IT IS FURTHER ORDERED that a hearing on Plaintiffs' motion for a preliminary injunction shall be held on the __ day of _____, 2019, at _____a.m./p.m. in Department ____ of the above-entitled Court.

IT IS FURTHER ORDERED that this Order to temporarily restrain and enjoin the conduct of the Board shall remain in effect until the hearing on a preliminary injunction, unless further extended, or modified by order of this Court or stipulation of the parties.

DATED this ____ day of July, 2019

_____
DISTRICT COURT JUDGE

Respectfully submitted by:

/s/Constance L. Akridge
Constance L. Akridge
J. Malcolm DeVoy
Brittany L. Walker
HOLLAND & HART LLP
9555 Hillwood Drive, 2nd Floor
Las Vegas, NV 89134

13263309_v8

HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
LAS VEGAS, NV 89134

EXHIBIT C

Electronically Filed
8/8/2019 11:50 AM
Steven D. Grierson
CLERK OF THE COURT

ORDR

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DISTRICT COURT

CLARK COUNTY, NEVADA

ACRX SPECIALTY PHARMACY, INC. a Nevada corporation; and EGHOMWARE IGBINOVIA, a/k/a JERRY IGBINOVIA, an individual,

Plaintiffs,

v.

NEVADA STATE BOARD OF PHARMACY; DOES I-X; and ROE CORPORATIONS XI-XX,

Defendant.

Case No. A-19-798928-C
Dept. No. II

ORDER GRANTING PLAINTIFFS' EX PARTE APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION, AND SETTING HEARING ON PRELIMINARY INJUNCTION

Hearing Date: July 26, 2019
Hearing Time: 9:00 a.m.

On July 26, 2019 at 9:00 a.m., the matter of Plaintiffs' Ex Parte Motion for Temporary Restraining Order and Preliminary Injunction, submitted to the Court on July 22, 2019 on an Order Shortening Time by Plaintiffs ACRX Specialty Pharmacy Inc. ("ACRX") and Eghomware Igbinovia, a/k/a Jerry Igbinovia ("Igbinovia"), collectively the "Plaintiffs," came on for hearing and was argued by Constance L. Akridge, Esq. and J. Malcolm DeVoy, Esq. of Holland & Hart LLP for Plaintiffs, and Brett Kandt, Esq. of the Nevada State Board of Pharmacy ("Board," or the "Defendant") for Defendant.

AUG 0 2 2019

This Court, having reviewed Plaintiffs' Motion and all attachments, the Complaint filed herein, considered the arguments of counsel for both Plaintiffs and Defendant, counsel for Plaintiffs having provided copies of the Motion and Complaint to general counsel for Defendant, and good cause appearing, hereby finds that this is a proper instance for a temporary restraining order to be issued because if Defendant is not restrained and enjoined by order of this Court, Plaintiffs will suffer immediate and irreparable injury through deprivation of their valid business interests and damage to their property interests in their professional licenses issued and governed by the Board. In addition to the declarations supporting the Motion pursuant to Nev. R. Civ. P. 65(b)(2), the Court makes the following findings of fact and conclusions of law as a basis for this Order as required by Nev. R. Civ. P. 65(d)(1)(A)-(C):

I. FINDINGS OF FACT

1. On June 20, 2019, the Nevada State Board of Pharmacy ("Board") involuntarily closed ACRX when law federal enforcement agencies seized nine (9) computers from ACRX and arrested Igbinovia. Despite these events, Igbinovia was processed and released from custody on his own recognizance that very same day, without the requirement to post any bond.

2. Igbinovia submitted evidence to the Court that he had maintained a backup of all data found on the nine (9) computers seized from ACRX by law enforcement officers.

3. Neither the Board nor any other governmental entity has obtained any order or other form of relief requiring ACRX to close.

4. The Board neither complied with NRS 233B.127(3) nor intended that its actions constitute a summary suspension of ACRX's pharmacy license under this provision.

5. Before the hearing, the Board had refused to re-open ACRX.

6. Patients who are not parties to this action have been affected by the Board's actions, and have had their access to medication disrupted by the Board's closure of ACRX; the Court finds that those affected patients' needs for prescribed, necessary, and life-saving medications is the most relevant measure of the public's interest in any injunctive relief.

7. Plaintiffs and Defendant have represented and stipulated through their above-identified counsel that any Temporary Restraining Order shall be converted into a Preliminary

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Injunction and remain in effect through the date of the Preliminary Injunction hearing specified within this Order.

II. CONCLUSIONS OF LAW

1. The provisions of NAC 639.570 and NRS 639.070 do not permit the Board to close ACRX and exclude Plaintiffs from the pharmacy's location without adequate notice and hearing required under NRS 233B.121 and 233B.127. Instead, NAC 639.570 merely prescribes procedures for the Board to follow in the event of an involuntary closure of a pharmacy as a result of governmental action, which has not happened in this case. *See* NAC 639.570(5).

2. Plaintiffs have shown a reasonable probability of success on the merits of their claims against Defendant.

3. Plaintiffs have shown a reasonable probability of demonstrating they are suffering and will continue to suffer irreparable harm if this Court does not issue an injunction.

4. The public interest, balancing both the need to constrain governmental action according to the terms of the Nevada Revised Statutes and the Nevada Administrative Code, and the public's interest in enforcing laws regarding the distribution of regulated drugs, weigh in favor of this Court granting the Plaintiffs' motion and allowing ACRX to re-open, restoring the status quo that existed before the Board's June 20, 2019 closure of the pharmacy.

5. The Court finds that the circumstances and conditions presented by Plaintiffs are exigent and, due to the threatened harm to Plaintiffs' business, warrants immediate relief in the form of the temporary restraining order granted herein.

Accordingly, for all the foregoing reasons:

IT IS HEREBY ORDERED that a Temporary Restraining Order shall be issued pursuant to Nev. R. Civ. P. 65(b) restraining Defendant from further restricting Plaintiffs from operating their pharmacy pursuant to the Board's June 21, 2019 Notice of Involuntary Closure;

IT IS FURTHER ORDERED that, pursuant to the stipulation of Plaintiffs and Defendant made on the record before this Court, the Temporary Restraining Order shall be converted into a Preliminary Injunction under Nev. R. Civ. P. 65(d), and continue in effect through the date of the hearing specified within this Order;

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IT IS FURTHER ORDERED that the Board is hereby ENJOINED from any continued enforcement of its June 21, 2019 Notice of Involuntary Closure against Plaintiffs, including the denial of access to ACRX and cessation of its operations pursuant to that notice;

IT IS FURTHER ORDERED that the Board is hereby ENJOINED from denying Plaintiffs access to their place of business pursuant to its June 21, 2019 Notice of Involuntary Closure;

IT IS FURTHER ORDERED that the foregoing provisions of this Order, and the Court's purpose and intent in entering this Order, shall not be construed to impair or limit the Board's authority to regulate Plaintiffs in conformity with Nevada law;

IT IS FUTHER ORDERED that the Board shall allow Plaintiffs to reopen ACRX *forthwith* and without delay, including conducting all necessary reviews and inspections prior to ACRX re-opening, and the Board shall take all steps necessary to restore Plaintiffs' access to ACRX's facilities immediately upon receipt of this Order;

IT IS FURTHER ORDERED that, pursuant to Nev. R. Civ. P. 65(c), Plaintiffs shall file a bond for costs and damages that may be incurred by any party who may be found to be wrongfully restrained or enjoined from this Order in the total sum of $500.00;

IT IS FURTHER ORDERED that an evidentiary hearing on Plaintiffs' motion for a preliminary injunction shall be held on the 5th day of September, 2019, at 10:00 a.m. in Department II of the above-entitled Court;

IT IS FURTHER ORDERED that two weeks prior to the September 5, 2019 evidentiary hearing, the parties shall exchange lists identifying their proposed witnesses and the documents they intend to rely upon at that hearing, provided further that each party must provide immediate notice to opposing counsel identifying any witnesses presented at the Board's September 4, 2019 hearing regarding Plaintiffs that could not have been previously disclosed; and

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LAS VEGAS, NV 89134

IT IS FURTHER ORDERED that this Preliminary Injunction shall be in effect and enjoin the conduct of the Board until the September 5, 2019 hearing specified above, unless further extended, or modified by order of this Court or stipulation of the parties.

DATED this ____ day of August, 2019.

DISTRICT COURT JUDGE
A798928

Respectfully submitted by:

Constance L. Akridge, Esq.
S. Malcolm DeVoy, Esq.
Brittany L. Walker, Esq.
HOLLAND & HART LLP
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Las Vegas, NV 89134

Attorneys for Plaintiffs

Approved as to form:

Brett Kandt, Esq.
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch parkway # 206
Reno, NV 89521

Attorney for Defendant

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LAS VEGAS, NV 89134

IT IS FURTHER ORDERED that this Preliminary Injunction shall be in effect and enjoin the conduct of the Board until the September 5, 2019 hearing specified above, unless further extended, or modified by order of this Court or stipulation of the parties.

DATED this 2nd day of August, 2019.

DISTRICT COURT JUDGE

TM

Respectfully submitted by:

Constance L. Akridge, Esq.
J. Malcolm DeVoy, Esq.
Brittany L. Walker, Esq.
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EXHIBIT D

ACRx SPECIALTY PHARMACY
YOUR STERIL AND NON-STERILE LOCAL COMPOUNDING PHARMACY

April 5, 2019

Department of Health and Human Services
Food and Drug Administration
ATTN: Bryan L Mcguckin, Investigator
1431 Harbor Bay Parkway
Alameda, CA 94502

RE: ACRX Specialty Pharmacy Inc Response to FDA Form 483, FEI # 3015134033

Dear Mr. Mcguckin,

The FDA conducted a routine inspection of our pharmacy, ACRX Specialty Pharmacy Inc ("ACRX") on 02/25/2019 through 03/01/2019 and on 03/06/2019, 03/07/2019, and 03/20/2019. At the conclusion of the inspection, an FDA Form 483 listing nine (9) observations was issued. Enclosed you will find our responses to these 9 observations and pertinent documentation to serve as evidence of corrective actions taken.

ACRX wishes to emphasize that it takes the inspectional observations detailed in the FDA Form 483 very seriously. As ACRX strives to provide our patients with safe and efficacious compounded preparations, we are committed to adhering to applicable laws and regulations that ensure patient safety and the preparation of high-quality compounded medications. Since the receipt of the FDA Form 483, ACRX has undertaken the process of assessing and updating our compounding operations and standard operating procedures ("SOPs") as part of our efforts towards continuous quality improvement.

At the time of the FDA inspection, ACRX was engaged in what we presumed to be the lawful practice in Nevada of dispensing prescriptions for "office use. ACRX has notified all prescribers who have previously ordered compounded preparations for "office use" that, effective 03/11/2019, we will no longer fulfill these orders and that all compounded preparations will only be dispensed pursuant to a patient-specific prescription. {Prescribers were notified via a telephone call on 03/07/2019 and a follow-up written notification was sent on 04/08/2019. A copy of the notification sent to physicians is enclosed for your reference (Attachment 1)}. As all compounded preparations shall only be dispensed pursuant to the receipt of a valid prescription by a licensed practitioner for an individually-identified patient, the compounded products prepared by ACRX are eligible for the exemptions allowed by Section 503A of the Food, Drug, and Cosmetic ("FD&C") Act, including an exemption from the requirement for conformance with current Good Manufacturing Practices ("cGMPs").

ACRX will provide the Agency with a status update on the commitments detailed in the responses below within thirty (30) days of this letter. Included in the status update will be documentation to serve as evidence of the corrective actions that have been taken, including updated SOPs and training files, as appropriate.

ACRx SPECIALTY PHARMACY
YOUR STERIL AND NON-STERILE LOCAL COMPOUNDING PHARMACY

In conclusion, we hope this response demonstrates our continued commitment to patient safety and continuous quality improvement. Thank you for your consideration of this response. If you should have any questions, please do not hesitate to contact Eghomware (Jerry) Igbinovia, RPh via telephone at 702-595-6265 or via email at jerry@acrxpharmacy.com.

Sincerely,

Eghomware J. Igbinovia, RPh, Owner
ACRX Specialty Pharmacy Inc

Observation 1:

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically, on 02/26/2019 during the production of sterile products I observed the following:

A) Multiple exits and entries from the cleanroom, to attain supplies from classified and unclassified zones without disinfecting or changing garbing.

Response to Observation 1.A

ACRX engaged the assistance of a qualified consultant with relevant experience in aseptic processing operations to perform an onsite assessment of our aseptic technique and conduct an in-service training of sterile compounding personnel. Jerry Igbinovia, RPh and owner, is the sole individual engaged in sterile compounding activities at ACRX, and is the individual who received the training detailed below.

On April 3rd, 2019, this assessment and re-training was performed by Dr. Ross Caputo, President of Eagle. Enclosed is the training letter issued by Eagle (Attachment 2), the completed observational competency assessment used to evaluate the aseptic technique of the sterile compounder (Attachment 3), and a copy of Dr. Caputo's CV as documentation of his credentials (Attachment 4).

Training was provided on proper staging of supplies and materials during aseptic processing operations. Specifically discussed were processes for staging all supplies prior to initiating sterile compounding and disinfecting supplies as they are moved from areas of lower quality air cleanliness to areas of higher quality air cleanliness. Also emphasized were the requirements to change garb whenever personnel exit and re-enter the sterile cleanroom from unclassified areas and to disinfect gloved hands when exiting or re-entering the ISO 7 buffer room or ISO 5 laminar airflow hood ("LAFH").

ACRX will review and update our SOPs to emphasize the requirements to minimize movement between classified areas during aseptic processing, to disinfect supplies as they are moved between ISO classified areas, to stage all supplies prior to initiating aseptic processing, and to change sterile garb whenever the cleanroom is exited and re-entered from an unclassified zone.

Timeline: Effective immediately, ACRX will implement the changes in personnel and material flow and garbing discussed. Applicable SOPs shall be revised and submitted to the FDA for review within 30 days.

B) Sterile clothing (suit & gloves) used to clean and disinfect the clean-room was not replaced prior to production of sterile drug products.

Response to Observation 1.B

During the FDA inspection, the Investigator observed the sterile compounder conduct routine morning cleaning operations including sanitization of the ISO 5 LAFH, disinfection of storage bins and shelving, and mopping of the floors in ISO-classified areas. ACRX will revise its SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility" to only require that the ISO 5 is disinfected in the morning before sterile compounding activities begin so that sterile garb does not need to be replaced prior to initiating compounding activities. Full cleaning, including disinfection of storage bins and mopping floors, will be performed at the end of the day after sterile compounding activities have ceased.

SOP 9.100 "Required Garb for Clean Room Facility Access" will be updated to require that sterile compounders replace their sterile suit and gloves in the event that a full cleaning of the sterile compounding area is required at the beginning of the day.

As stated in the response to Observation 1.A, the onsite training session conducted by Dr. Caputo of Eagle addressed the requirement that sterile garb is changed prior to initiating sterile compounding if cleaning activities have been performed (Attachment 2).

Timeline: Effective immediately, sterile compounders shall change sterile suit and gloves prior to initiating sterile compounding in the event of a full cleaning of the clean room. SOPs 3.020 and 9.100 shall be revised and submitted to the FDA within 30 days.

C) Supplies used to manufacture sterile products were left inside of the ISO5 LAFH in a manner which could disrupt unidirectional airflow.

Response to Observation 1.C

The placement of supplies and components used during the sterile compounding process was addressed during the onsite training conducted by Dr. Caputo. Specifically, instruction to only bring supplies into the ISO 5 LAFH that are necessary for a given batch being compounded was provided. (Attachments 2, 3, 4).

Additionally, the placement of supplies in the ISO 5 LAFH during sterile compounding will be evaluated by an upcoming air pattern analysis via smoke studies (further addressed in response to Observation 1.D). The smoke study will be conducted under dynamic conditions. In order to confirm that unidirectional airflow is not blocked or disrupted, supplies and components used to compound the largest batch size typically prepared by ACRX will be brought into the ISO 5 LAFH and aseptic processing operations will be simulated. If the results of the smoke study indicate that the placement of supplies does disrupt or block airflow, the method of placing supplies will be re-assessed to ensure that no airflow disruption occurs.

Timeline: A smoke study will be conducted under dynamic conditions on 04/11/2019. The video will be reviewed and approved by ACRX. A copy of the video of the smoke study shall be provided to the FDA within 30 days.

D) Sterile 70% IPA was opened and refilled during production.

Response to Observation 1.D

SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility" will be revised to require that sterile 70% IPA, which is purchased in a "ready to use" configuration, is not re-opened or refilled. Sterile 70% IPA shall only be opened inside of the ISO 5 LAFH in order to initially puncture the bottle. All sterile 70% IPA that has been opened or re-opened outside of the ISO 5 LAFH or that has been refilled has been discarded.

Timeline: SOP 3.020 will be revised and submitted to the FDA for review within 30 days.

E) Sterile wipes used during sterile production were observed open on a cart inside the anteroom and buffer zone.

Response to Observation 1.E

The sterile wipes observed by the Investigator are purchased from the manufacturer in a package that is not re-sealable once opened. In order to address this observation, ACRX has sourced sterile wipes stored in re-sealable packaging from VWR. In order to protect the sterility of the wipes, ACRX will update its SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility" to require that the packaging is only opened inside of the ISO 5 LAFH. If the package of sterile wipes needs to be removed from the ISO 5 environment, they will first be re-sealed.

ACRX will only open their current supply of sterile wipes inside the ISO 5 LAFH. Since the packaging cannot be re-sealed, they will be stored under ISO 5 conditions. Any sterile wipes that have been opened or stored out of the ISO 5 LAFH have been discarded.

Timeline: SOP 3.020 will be revised and submitted to the FDA for review within 30 days.

On 03-06/2019 I observed the following:

A) Sterile garbing hanging next to the clean room for reuse, per the PIC.

Response to Observation 1.A

Under past policy, sterile garbing may be hung in the clean room and re-used only during the same work shift. This practices complies with USP <797> requirements, which state that "when compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during the same work shift only" (p. 30). It is also compliant with NV BOP regulations which state that "a gown may be used more than once within a 12-hour period if it is removed in the ante-area and is stored in the ante-area until it is used again" (NAC 639.6705 1(d)(3)).

However, in order to assure that the sterility of the garb is maintained, ACRX will revise its SOP 9.100 "Required Garb for Clean Room Facility Access" to prohibit re-use of sterile garb during the same work shift. If the clean room facility must be exited, sterile garb shall be discarded, and new sterile garb shall be donned upon re-entry.

Timeline: SOP 9.100 will be revised and submitted to the FDA for review within 30 days.

B) Equipment used to depyrogenate glassware has never been qualified or calibrated.

Response to Observation 1.B

ACRX will update SOP 4.020 "Use, Calibration and Maintenance of the Fisher Isotemp 725F Dry-Heat Oven" to require that the depyrogenation cycle of the convection oven is verified on at least an annual basis or whenever the loading configuration is changed. The depyrogenation cycle that is used to depyrogenate glassware will be verified through the use of endotoxin challenge vials (ECV), which shall be laboratory tested to confirm that the depyrogenation cycle is capable of achieving ≥3-log reduction in endotoxin levels.

Additionally, ACRX has purchased and received a certified NIST-traceable thermometer in order to confirm the temperature of the convection oven cycles (Attachment 5– purchase order/receipt). The thermometer will either be replaced or re-certified on an annual basis.

Timeline: The results of the depyrogenation cycle verification and the revised SOP 4.020 will be submitted to the FDA for review within 30 days.

C) Equipment used in terminal heat sterilization has never been qualified or calibrated.

Response to Observation 1.C

ACRX will updates its SOP 4.030 ""Use, Verification, and Maintenance of the Tuttnauer EZ10 Electronic Tabletop" to require that the effectiveness of the terminal heat sterilization cycle is verified through use of appropriate biological indicators (BIs) on an at least annual basis, or whenever loading configurations are changed.

Additionally, ACRX has purchased and received a certified NIST-traceable thermometer in order to confirm the temperature of the autoclave cycles (Attachment 5 – purchase order/receipt). The thermometer will either be replaced or re-certified on an annual basis

Timeline: The results of the terminal heat sterilization cycle verification and the revised SOP 4.030 will be submitted to the FDA for review within 30 days.

D) Dynamic smoke studies have not been conducted.

Response to Observation 1.D

Previously, smoke studies of the ISO 5 LAFH under static conditions have been conducted at each biannual clean room facility re-certification. ACRX will revise its SOP 3.010 "Sterile Compounding Area

Requirements" to require that smoke studies of the ISO 5 LAFH are conducted under dynamic operating conditions during each biannual re-certification.

ACRX has scheduled for CEM to perform a smoke study under dynamic conditions on 04/11/2019. Enclosed is a copy of the work order from CEM (Attachment 6) to serve as documentation of this scheduled testing.

Timeline: A smoke study under dynamic conditions will be performed on 04/11/2019 and biannually thereafter. The video will be reviewed and approved by ACRX. A video copy of the smoke study and the revised SOP will be provided to the FDA for review within 30 days.

E) Media fills are conducted biannually but do not include the most challenging process performed.

Response to Observation 1.E

ACRX will update its media-fill procedure, SOP 9.110 "Sterile Compounding Process Validation (Media Fills)," to require that the media-fill testing that is performed biannually is reflective of the most challenging and stressful conditions encountered during routine sterile compounding operations. Specifically, the revised media-fill test will simulate the most complex aseptic processing activities and will include planned interventions.

ACRX has purchased non-sterile TSB media to use during this media-fill challenge (Attachment7 – purchase order). Upon receipt of this media, the sterile compounder at ACRX will perform the revised media-fill test procedure.

Timeline: SOP 9.110 will be revised, and a media-fill test will be performed. A copy of the revised SOP and of the media-fill test results shall be submitted to the FDA for review within 30 days.

F) Load mapping studies have never been conducted to qualify the terminal heat sterilization process.

Response to Observation 1.F

Verification studies will be conducted to qualify the terminal heat sterilization process. Please see response to Observation 1.C for further detail.

Observation 2:

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

A) Environmental monitoring of ISO classified zones is conducted on a biannual basis only.

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Response to Observation 2.A

As a 503A compounding facility, ACRX is compliant with the USP <797> requirements for biannual environmental monitoring of ISO classified zones through viable air and surface sampling. USP <797> states that "Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally...as part of the re-certification of facilities and equipment (i.e., every 6months)" (p. 23).

However, ACRX is committed to not solely adhering to the requirements outlined in USP <797> and the NV BOP regulations, but to implementing best practices in our operations to ensure environmental control. As such, we will implement monthly environmental monitoring by performing surface sampling and active air sampling via impaction. We will update our SOP 3.030 "Environmental Monitoring of the Clean Room Facility" to reflect the revised frequency of environmental monitoring activities and create a detailed sampling plan.

Timeline: SOP 3.030 will be revised and submitted to the FDA for review within 30 days.

B) Pressure differentials between classified and unclassified areas are not monitored daily.

Response to Observation 2.B

Currently, ACRX documents pressure differentials between classified and unclassified areas only on days when sterile compounding occurs prior to initiating sterile compounding activities.

ACRX will revise SOP 3.020 to require that pressure differentials are documented on all days that the pharmacy is open, regardless of whether sterile compounding activities are scheduled to occur. Additionally, ACRX will follow SOP 9.020 "Good Documentation Practices" to ensure that appropriate notations are made on the pressure differential log on days where pressure differentials are not documented to indicate that the pharmacy was closed.

Timeline: SOP 3.020 will be revised and submitted to the FDA for review within 30 days.

C) Personnel monitoring is conducted using samples taken from the gloved hands of employees following sterile drug production on a biannual basis only.

Response to Observation 2.C

As a 503A compounding pharmacy, ACRX is compliant with the USP <797> requirements for biannual gloved fingertip sampling in conjunction with media-fill testing. USP <797> states that "after completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs using one or more sample collections during any media-fill test" (p. 32). Additionally, ACRX is compliant with NV BOP requirements, which require that "the pharmacist or pharmaceutical technician provide a sample for a gloved fingertip sampling which must be conducted in the manner provided by chapter 797 of the *United States Pharmacopeia – National Formulary*" (NAC 639.67053(2)(a)).

However, ACRX is committed to implementing best practices in our operations to ensure the adequacy of personnel garbing and aseptic practices. As such, we have decided to implement personnel monitoring through post-compounding gloved fingertip sampling on a monthly basis. We will revise our SOP 2.030 "Sterile Compounding Personnel Qualification" to require that gloved fingertip sampling is performed post-compounding on a monthly basis.

Timeline: SOP 2.030 will be revised and submitted to the FDA for review within 30 days.

D) Alarm systems to monitor for potential breaches in air quality are currently not employed. For example, I observed a sliding door between the ISO 8 classified ante-room and unclassified zone that was held open during sterile drug production on 02/26/2019 to gather supplies.

Response to Observation 2.D

As a 503A compounding pharmacy, alarm systems to monitor for potential breaches in air quality are not required. Rather, USP <797> requires that "a pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily" (p. 24). ACRX will comply with these requirements by monitoring and documenting pressure differentials between classified and unclassified zones on all days when the pharmacy is open.

In order to minimize the potential for influx of lower quality air into the ISO classified areas, ACRX sterile compounding personnel have immediately ceased the practice of holding the door open between the ISO 8 ante-room and the unclassified area. If sterile compounding personnel must gather supplies from the unclassified area, they will exit the cleanroom facility to gather such supplies and replace all sterile garb upon re-entry into the ISO 8 ante-room.

Timeline: Effective immediately.

Observation 3:

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, extended BUDs are established for multiple products without the appropriate data.

Sterility and potency data was observed for these products however no other data was provided.

Accelerated studies were either not conducted or data was not provided after multiple requests, that demonstrates there are no degradant products formed or potency altered under such conditions.

Furthermore, I observed ingredient stock solutions used in multiple Vita-B Complex formulations. These stock solutions are used for multiple products, requiring multiple extractions during extended use.

Response to Observation 3

Upon ceasing the practice of dispensing "office-use" prescriptions, ACRX meets the requirements for eligibility for exemptions from certain sections of the FD&C Act under Section 503A, including the requirement for conformance with cGMPs. As such, ACRX must comply with applicable USP chapters related to pharmacy compounding and state Board of Pharmacy regulations.

USP <795> and USP <797> allow compounding pharmacies to use potency testing, professional judgement, and appropriate literature references to assign beyond-use dates (BUDs) to compounded preparations. Specifically, "when assigning a beyond-use date, compounding personnel should consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy" (p. 40). Additionally, for high-risk level CSPs, NV BOP states that "unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a high-risk sterile compounded product must not exceed (a) twenty-four hours at a controlled room temperature that is at least 20 degrees Celsius but not more than 25 degrees Celsius (b) Three days at a temperature that is at least 2 degrees Celsius but not more than 8 degrees Celsius (c) Forty-five days in a solid frozen state that is -10 degrees Celsius or colder" (NAC 693.67067). Since sterility and potency testing has been conducted on all CSPs prepared by ACRX, the BUDs may exceed the dates in the NAC reference.

In order to comply with these requirements, ACRX has performed potency testing every 30-60 days over the course of the shelf-life of the product in order to establish the BUD and ensure that the CSP remains in conformance with potency specifications until the end of the beyond-use dating period. Documentation of all potency testing was provided to the Investigator. These studies were performed on the CSP in the actual container-closure system in which it will be stored and dispensed and under the actual storage conditions of the product. Additionally, a USP <71> sterility test was performed on all CSPs in order to confirm the sterility of the finished compounded preparation.

ACRX has also tested all stock solutions for sterility and for potency over the course of the shelf-life of the product. Additionally, all stock solutions contain an anti-microbial preservative, and are used in accordance with USP <797> requirements for multi-dose containers, which states that "the BUD after initially entering or opening (e.g., needle puncturing) multiple-dose containers is 28 days, unless otherwise specified by the manufacturer" (p. 41). Any stock solution that has been punctured more than 28 days ago or if the puncture date is unknown has been discarded.

In response to the observation that there is no written stability testing program, ACRX will update its SOP 9.050 "Beyond-Use Dating" to reflect the testing requirements outlined above.

Timeline: SOP 9.050 will be revised and submitted to the FDA for review within 30 days.

Observation 4:

The distribution system is deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically, you are currently using an off the shelf program with lot tracking functionality. However, you have not instituted a data entry or report procedure to ensure that Rx information is cross referenced to specific lots. Multiple requests to track specific lot information via Rx information could not be performed by the PIC or the assistant Pharmacist. No specific lot could be identified for the Rx's requested.

Response to Observation 4:

ACRX maintains documentation of Master Formula Worksheets and Compounding Batch Records in PK Compounding software. Patient prescription records are maintained within the dispensing software, WIN RX. While it is ACRX procedure that the lot number of all compounded preparations dispensed is linked to the patient prescription in WIN RX software, pharmacy personnel failed to document the lot number of the compounded preparation to the patient for the prescriptions referenced in Observation 4. In order to correct this deficiency, ACRX personnel were re-trained on 03/11/2019 on the requirements for documenting the lot number of the compounded preparation associated with patient prescriptions dispensed. Training of this documentation is enclosed (Attachment 8).

ACRX will write a procedure that requires that lot numbers are documented on the appropriate records for traceability purposes. All ACRX personnel will be trained on this new procedure, and such training will be documented.

Timeline: An SOP will be written and personnel will be trained on the new SOP. The new SOP and documentation of personnel training shall be submitted to the FDA for review within 30 days.

Observation 5:

Written procedures for cleaning and maintenance fail to include maintenance and cleaning schedules, description in sufficient detail of methods, equipment and materials used, description in sufficient detail of the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance, instructions for protection of clean equipment from contamination prior to use and parameters relevant to the operation.

Specifically, there were no cleaning SOP's to review which demonstrate actual procedures utilized. A generic, commercially available template SOP was provided by lacked any supporting information that would reflect actual practices at your firm as described by the PIC.

Cleaning practices observed on 02/26/2019 prior to sterile drug production were not reflected in SOP#: 3.020 "Cleaning and Maintenance of The Clean Room Facility". Furthermore, the PIC confirmed on 02/26/2019 and 02/28/2019 that most SOP's at the facility have not been modified to reflect actual practices at the firm.

Response to Observation 5:

SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility" will be revised in order to reflect the actual cleaning procedures utilized by ACRX. The revised SOP is specific to the cleaning and maintenance schedule of the sterile compounding areas and provides detailed descriptions of cleaning methods, disinfectants, and materials used.

In response to the observation that "most SOP's at the facility have not been modified to reflect actual practices at the firm," ACRX has committed to undertaking a comprehensive evaluation of its SOP manual. All SOPs that do not reflect actual practices will be updated accordingly.

Timeline: SOP 3.020 will be revised and submitted to the FDA for review within 30 days. A schedule and update on the progress of the SOP review will be provided to the FDA within 30 days.

Observation 6:

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, sterility and endotoxin testing are not conducted on finished sterile drug products.

Response to Observation 6:

ACRX complies with NV BOP testing requirements for sterility and endotoxin testing of sterile preparations. Specifically, NV BOP regulations require that sterility and endotoxin testing for injectable preparations are performed under the following conditions: "(1) A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for injection into the vascular system or central nervous system shall test a quantity of the high-risk sterile compounded drug product for (a) Sterility using a membrane filtration method or equivalent method...(b) Excessive bacterial endotoxin using an appropriate test" (NAC 639.67071).

NV BOP regulations also require that sterility testing for CSPs for ophthalmic or inhalation use is performed under the following conditions: "(2) A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for inhalation or ophthalmic use shall test a quantity of each such high-risk sterile compounded drug product for sterility" (NAC 639.67071).

Lastly, NV BOP regulations state that "the provisions of subsections 1 and 2 apply only to high-risk sterile compounded drug products: (a) Compounded in groups of more than 25 identical individual single-dose packages; (b) Compounded in multiple-dose vials for administration to multiple patients; or (c) That will be exposed for a period of more than: (1) Twelve hours to temperatures of at least 2 degrees Celsius but not more than 8 degrees Celsius; (2) Six hours to temperatures of exceeding 8 degrees Celsius before the compounded drug product is sterilized" (NAC 639.67071).

21 CFR Part 211.167(a) requires that "for each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements". Upon ceasing the practice of dispensing "office-use" prescriptions on 03/11/2019, ACRX meets the requirements for eligibility for exemptions from certain sections of the FD&C Act under Section 503A. ACRX, therefore, is eligible for an exemption from the requirement for conformance with cGMPs, including 21 CFR Part 211.167(a).

ACRX-compounds only small batches of sterile preparations that do not exceed 20 units and therefore do not require sterility or endotoxin testing under NV BOP laws. However, in order to collect data that demonstrates the assurance of the sterility and apyrogenicity of sterile preparations, ACRX commits to testing at least two batches per month for sterility and bacterial endotoxin levels, regardless of the batch sizes prepared. ACRX will revise its SOP 9.120 "Sterile Compounding Finished Preparation Testing" to reflect these testing requirements.

Timeline: SOP 9.120 will be revised and submitted to the FDA for review within 30 days.

Observation 7:

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, potency testing is not conducted on finished drug products prior to release.

Response to Observation 7:

ACRX complies with USP Chapters <795> and <797> and NV BOP regulations for potency testing. Under these regulations, there are no requirements for testing the potency of finished drug products prior to release.

21 CFR Part 211.165(a) requires that "for each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release". Upon ceasing the practice of dispensing "office-use" prescriptions on 03/11/2019, ACRX meets the requirements for eligibility for exemptions from certain sections of the FD&C Act under Section 503A. ACRX, therefore, is eligible for an exemption from the requirement for conformance with cGMPs, including 21 CFR Part 211.165(a).

In order to collect data that demonstrates that compounding processes are reproducible and result in finished drug products that conform with potency specifications, ACRX will follow PCAB accreditation standards for personnel proficiency testing and will implement a routine potency testing program. ACRX will revise its SOPs 2.030 "Sterile Compounding Personnel Qualification" and 2.040 "Non-Sterile Compounding Personnel Qualification" in accordance with the industry guidelines established by PCAB.

Timeline: SOPs 2.030 and 2.040 will be revised and submitted to the FDA for review within 30 days.

Observation 8:

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, all complaint files were requested. Provided were two complaints over the past 12 months. The PIC stated that prior to 2018 a complaint file was not maintained. Review of the two complaints compiled demonstrated that complaints received are not investigated or reviewed by the PIC. Pertinent product information such as lot number is not provided. For example:

CC#1: Nature of problem "Black Specs Formed" does not provide lot, expiration, results or product name. No investigation was conducted nor explained why none was needed. The Completed/Reviewed By and date sections were left blank.

Response to Observation 8:

All pharmacy personnel have been re-trained on ACRX's SOP 5.030 "Complaint Handling" on 04/05/2019, and documentation of this training is enclosed (Attachment 9). SOP 5.030 requires that the following pertinent information is obtained from the individual filing the complaint and is documented on the Customer Complaint Record: customer name, date of occurrence, customer address and telephone number, the exact nature of the problem, whether any adverse events have occurred or may have occurred, and the lot number(s), expiration date(s), results, product name(s) related to the exact product in question. Personnel were also instructed to notify the PIC upon receipt of a written or oral complaint so that he may be involved in reviewing the complaint and the subsequent investigation. All of these critical aspects of complaint handling and documentation were addressed in the ACRX personnel training performed on 04/05/2019.

Additionally, ACRX will update SOP 5.030 "Complaint Handling" to require that the PIC review the complaint, initiate an investigation into the complaint to determine a probable root cause, extend the investigation to other batches which may have been affected, and determine appropriate corrective and preventative actions. The procedure will also require that an explanation is provided if it is determined that an investigation is not needed and documentation of the individual responsible for that decision. The updated SOP will also require that the PIC sign all Customer Complaint Records as documentation of review of the complaint.

Timeline: ACRX personnel were re-trained on SOP 5.030 on 04/05/2019. SOP 5.030 will be further revised and submitted to the FDA for review within 30 days.

Observation 9:

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, finished non-sterile drug products are not tested for the presence of microorganisms.

Response to Observation 9:

ACRX complies with USP Chapters <795> and <797> and NV BOP regulations. Under these regulations, there are no requirements for testing finished non-sterile drug products for the presence of objectionable microorganisms.

21 CFR Part 211.165(b) requires that "there shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms". Upon ceasing the practice of dispensing "office-use" prescriptions on 03/11/2019, ACRX meets the requirements for eligibility for exemptions from certain sections of the FD&C Act under Section 503A. ACRX, therefore, is eligible for an exemption from the requirement for conformance with cGMPs, including 21 CFR Part 211.165(b).

In order to collect data to demonstrate that finished non-sterile drug products compounded at ACRX are free from objectionable microorganisms, ACRX will revise its SOP 9.150 "Non-Sterile Compounding Finished Preparation Testing". The revised SOP will require that USP <62> testing for the presence of objectionable microorganisms is conducted on each non-sterile dosage form prepared at ACRX on an at least annual basis. Each dosage form will be tested for the presence of the objectionable

microorganism(s) that are listed in Table 1 of USP <1111>, "Microbiological Examination of Nonsterile Products," to ensure that it meets acceptance criteria for the microbiological quality of non-sterile drugs.

Timeline: SOP 9.150 will be revised and submitted to the FDA for review within 30 days.

ATTACHMENT 1

- **DISCONTINUATION OF OFFICE USE EMAIL TO DOCTORS**

DISCONTINUATION OF "OFFICE USE" ON ALL PRESCRIPTION ORDERS

admin acrxpharmacy.com

Mon 4/8/2019 3:48 PM

To: jerry acrxpharmacy.com <jerry@acrxpharmacy.com>;

Bcc: dwirtzdo@hotmail.com <dwirtzdo@hotmail.com>; charissacrandle@dgdentalservices.com <charissacrandle@dgdentalservices.com>; christina.apollomg1@gmail.com <christina.apollomg1@gmail.com>; jaimie@fdogv.com <jaimie@fdogv.com>; Info@imagenlaser.com <Info@imagenlaser.com>; md@mih.vegas <md@mih.vegas>; Brian@pushcompanies.com <Brian@pushcompanies.com>; vida@trimbodymd.com <vida@trimbodymd.com>; jillydoc@gmail.com <jillydoc@gmail.com>; lily@drdarrenwirtz.com <lily@drdarrenwirtz.com>; jaimie@fdogv.com <jaimie@fdogv.com>; lambert.abeyatunge@gmail.com <lambert.abeyatunge@gmail.com>; milka1172002@gmail.com <milka1172002@gmail.com>; Saloni Amin <saloni@regenerateme.com>;

Importance: High

We write further to the above and in respect of prescription orders filled as **OFFICE USE** at ACRX Specialty Pharmacy.

As you may already be aware, Acrx Specialty Pharmacy ceased accepting orders designated as **"Office Use"** with effect from **March 11, 2019.**

All orders filled at the pharmacy **MUST be patient specific.**

Should you have any queries, do not hesitate to contact the Pharmacy Manager.

We appreciate your business. Thank You!

Sincerely,
Jerry Igbinovia Pharm D
Pharmacy Manager

ATTACHMENT 2

- **TRAINING LETTER – EAGLE ANALYTICAL SERVICES**

EAGLE
SCIENCE-BASED SOLUTIONS

Eagle Analytical Services
9940 W. Sam Houston Pkwy. S, Suite 310
Houston, TX 77099
832.295.1276
www.eagleanalytical.com

Wednesday, April 3, 2019

Eghomware J. Igbinovia, RPh
ACRX Specialty Pharmacy Inc
3200 Soaring Gulls Drive, Ste. 101
Las Vegas, Nevada 89129

This letter is intended to document an onsite training session that was conducted by Dr. Ross Caputo, CEO and President of Eagle Analytical Services, Inc at ACRX Specialty Pharmacy Inc. on April 3, 2019. Enclosed is Dr. Caputo's CV as documentation of his credentials. This letter will be maintained in the pharmacy's training files along with two presentations, "Production of Sterile Products" and "Insanitary Conditions at Compounding Facilities," that provide more detailed documentation of the training conducted.

The training that was conducted focused on aseptic processing operations. Specifically, the training session focused on the following aseptic processing principles and techniques:

- Proper staging and disinfection of components and supplies when they are being moved from areas of lower quality air to areas of higher quality of air;
- Proper gowning procedures, including replacing all sterile garb upon exit and reentry into classified areas;
- Principles of working in a vertical laminar flowhood in a manner that does not disrupt unidirectional airflow or interfere with "first air";
- Proper handling of sterile components;
- Fundamentals of aseptic processing techniques;
- Appropriate sanitziation of gloved hands during the sterile compounding process.

Upon completion of training session, Dr. Caputo conducted an observational competency evaluation to assess the aseptic technique of the sterile compounder, as documented on the enclosed form, "Aseptic Technique and Contamination Control Competency Assessment".

Signature of Person Assessed	Printed Name	Date
Signature of Evaluator	Printed Name	Date

ATTACHMENT 3

COMPETENCY ASSESSMENT

Aseptic Technique and Contamination Control Competency Assessment

Employee: Jerry Igbinovia Rph Evaluator: Ross Caputo PhD Date: 4/3/19

This competency focuses on demonstrating knowledge and procedures that ensure proper aseptic technique and contamination control when performing sterile compounding.. The qualified evaluator will mark (X) each space for which the person being assessed has acceptably competed the described activity, print (N/A) if activity is not applicable, or (N/O) if activity was not observed).

Results	Criteria	Notes
X	Explains rationale for minimizing movement within the buffer room and ISO 5	
X	Sanitizes ISO 5 area before beginning compounding	
X	Sanitizes gloved hands before re-entering ISO 5 area whenever gloved hands are removed	
X	Sanitizes gloved hands whenever potentially nonsterile surfaces are touched	
X	Disinfects supplies/components when moving them from prep room to ante room	
X	Disinfects supplies/components when moving them from ante room to buffer room	
X	Disinfects supplies/components before placing them in ISO 5 area	
X	Removes outer wrapper, if applicable, from components before staging into ISO 5	
X	Does not bring papers (i.e. batch records) into ISO 5	
N/O	Demonstrates organized work flow which minimizes unnecessary movement in/out of buffer room	Had extended discussion about proper staging of all components before any sterile compounding begins to minimize movement between classified areas
X	Places components/supplies in ISO 5 in a manner which does not disrupt airflow	
X	Performs aseptic manipulations within ISO 5 critical area utilizing concept of first air	
X	Workflow direction is consistent; maintains a clean to dirty workflow direction	
X	Performs all manipulations at least 6 inches from front of ISO 5	
X	Vials/ports are disinfected with sterile 70% IPA prior to puncture	
N/A	Puts on new garb each time re-entry to controlled areas is required	
N/A	Changes gloves if they become damaged	
N/A	Compounds only one batch at a time in a given workspace	
X	Labels batches and in-process materials for lot number traceability	
X	Performs filter integrity test and documents psi (if applicable)	
X	Performs visual inspection of finished product	
X	Inspects finished product for expected appearance and container integrity	
X	Documents finished product checks on batch record	
N/A	Performs an area clearance prior to beginning a new batch	

Signature of Person Assessed	Jerry Igbinovia	4/3/19
	Printed Name	Date
Ross A Caputo	Ross A. Caputo	4/3/19
Signature of Evaluator	Printed Name	Date

ATTACHMENT 4

RESUME OF DR. CAPUTO AS DOCUMENTATION OF CREDENTIALS

Ross.caputo@outlook.com

Ross A. Caputo, Ph.D.

Objective Development of Technical Strategic Planning Initiatives

Professional Summary

Eagle Analytical Services Houston, TX 04/16 – Present
President

- Developing and implementing strategic plans to guide organization's vision, mission, and overall direction
- Guiding, directing, and evaluating the work of organization's executives
- Advise and direct all technical and scientific practices

Consultant 10/14 – 04/16

Retired 10/06 – 10/14

Pharmaceutical Systems Inc. Mundelein, IL 09/88 – 10/06
Founder, CEO

- Built analytical lab and CGMP consulting business to 150 employees
- Client base varied from start-up ventures, big Pharma, and DOD

Baxter Healthcare Chicago, IL 07/84 – 09/88
Director, Travenol Regional Compounding

- Built nationwide compounding pharmacy network
- Built nationwide oxygen repackaging network
- Developed standards for aseptic and hazardous drug processing

Hyland Diagnostics (Div. Baxter) Round Lake, IL 07/82 – 07/84
Director of Operations

- Responsible for all R&D, Quality, and Technical Activities
- Developed new home diagnostic tests

Baxter Travenol Morton Grove, IL 07/77 – 07/82
Director Corporate Microbiology

- Responsible for Sterilization validation of all Baxter products globally
- Developed standards for all validation requirements for steam, gas, and gamma sterilization, and aseptic processing operations
- Developed Biological Indicator for gas sterilization, 510K approved

Education

- Ph.D., Microbiology, Miami University, 1976
- M.S., Microbiology, Miami University, 1974
- B.S., Biological Science, Ohio State University, 1971

Publications

1. Caputo, R., A. Huffman, and R.R. Reich, 2005, "Practical Solutions for Microbiology, Sterility and Pyrogen Testing" in International Journal of Pharmaceutical Compounding, Vol. 9, No.1. January/February 2005. Pp 9-12.
2. Reich, R.R. and R. Caputo, 2004. "Vapor Phase Hydrogen Peroxide Resistance of Environmental Isolates" in Pharmaceutical Technology, August 2004.
3. M. Jeffrey, J. Koeller, J. Zdunek, R. Byrne, and R.A. Caputo, Validation of an Enhanced Method of Bacterial Ribotyping for Improved Efficiency and Identification of Stressed Isolates. *Pharm. Technol.* **28** (3), 156-165 (2004).
4. D. Khorzad, A. Khorzad, J. Herche, R.R. Reich and R.A. Caputo, Design and Operational Qualification of a Vapor-Phase Hydrogen Peroxide Biological Indicator Evaluator Resistometer (BIER) Unit. *Pharm. Technol.* **27** (11), 84-90 (2003).
5. R.A. Caputo Validation Testing of a Gas Plasma Sterilization System. Medical Device & Diagnostic Industry, January 1993.
6. R.A. Caputo Alternative Sterilization Technologies Come of Age, Gas Plasma Section. Medical Device & Diagnostic Industry, December 1992.
7. R.A. Caputo AbTox Plazlyte™ Plasma Sterilization. Journal of Healthcare Material Management, September 1992.
8. R.A. Caputo Biological Monitoring: Is your practice valid as well as cost effective? In 3M Healthcare Quarterly Newsletter, Infection Control Rounds, February 1991.
9. R.A. Caputo and T.E. Odlaug Sterilization with Ethylene Oxide and Other Gases. In Disinfection, Sterilization and Preservation. Ed. Seymor S. Block. Third Edition, Chapter 2, 1983.
10. T.E. Odlaug, V. Jarzynski, R.A. Caputo and C.C. Mascoli Evaluation of an Automated System for Rapid Identification of Bacillus Biological Indicators and Other Bacillus Species. Journal of Parenteral Science and Technology, March/April 1982.
11. R.A. Caputo, K.J. Rohn and C.C. Mascoli Biological Validation of an Ethylene Oxide Sterilization Process. Developments in Industrial Microbiology. Vol. 22, 1981.
12. T.E. Odlaug, R.A. Caputo and G.S. Graham Heat Resistance and Population Stability of Lyophilized *Bacillus subtilis* Spores. Applied and Environmental Microbiology, Vol. 41, 1981.
13. G.S. Graham, T.E. Odlaug, R.S. Schwabe and R.A. Caputo Effect of Growth Conditions on Sporulation and Heat Resistance of *Bacillus stearothermophilus* Spores. ASM Abstract, National Meeting, March 1981.

14. K.J. Rohn, D.L. Stryker and R.A. Caputo
Ethylene Oxide Resistance and Population Stability of *Bacillus subtilis* var. *niger* (*globigii*) Spores on Various Carrier Materials. ASM Abstract, National Meeting, March 1981.
15. T.E. Odlaug, R.A. Caputo and G.S. Graham
Heat Resistance and Population Stability of Lyophilized *Bacillus subtilis* Spores. ASM Abstract National Meeting, March 1981.
16. R.A. Caputo and C.C. Mascoli
Design and Use of Biological Indicators for Sterilization Cycle Validation. Medical Device and Diagnostic Industry, August 1980.
17. R.A. Caputo, K.J. Rohn and C.C. Mascoli
Biological Validation of an Ethylene Oxide Sterilization Process. Society for Industrial Microbiology National Meeting August 1980. Developments in Industrial Microbiology, 1981.
18. T.E. Odlaug, R.A. Caputo and C.C. Mascoli
Determination of Sterilization Values by Microbiological Methods. Society for Industrial Microbiology National Meeting, August 1980. Developments in Industrial Microbiology, 1981.
19. R.A. Caputo, T.E. Odlaug and C.C. Mascoli
The Effect of Heat Shock Treatment on the D and Z Value of *Bacillus* Spores. ASM Abstract National Meeting, May 1980.
20. R.A. Caputo, K.J. Rohn and C.C. Mascoli
Recovery of Biological Indicator Organisms After Sublethal Sterilization Treatment. Journal of Parenteral Drug Association, July/August 1980.
21. R.A. Caputo
Design and Use of Biological Indicators for Sterilization Cycle Validation. Proceedings of PMA Seminar on Biological Indicators, February 25-27, 1980.
22. R.A. Caputo, T.E. Odlaug; R.L. Wilkinson and C.C. Mascoli
Biological Validation of a Steam Sterilized Product by the Fractional Exposure Method. Journal of the Parenteral Drug Association, Vol. 33, 4 July/August, 1979.
23. K.J. Rohn and R.A. Caputo
Post Sterilization Stability of Ethylene Oxide Biological Indicators (*B. subtilis* var. *niger*). ASM Abstract, National Meeting, May 1979.
24. R.A. Caputo, T.E. Odlaug, R.L. Wilkinson and C.C. Mascoli
Biological Validation of a Sterilization Process for a Parenteral Product-Fractional Exposure Approach. ASM Abstract, National Meeting, May 1979.
25. K.J. Rohn and R.A. Caputo
Post Sterilization Stability of Ethylene Oxide Biological Indicators (*B. subtilis* var. *niger*). ASM Abstract, National Meeting, May 1979.
26. R.A. Caputo, T.E. Odlaug, R.L. Wilkinson and C.C. Mascoli
Biological Validation of a Sterilization Process for a Parenteral Product-Fractional Exposure Approach. ASM Abstract, National Meeting, May 1979.
27. R.L. Wilkinson and R.A. Caputo
Heat Resistance of *Bacillus subtilis* 5230 Spores in Parenteral Solutions-Determination of a Model Substrate for the Biological Validation of Sterilization Processes. ASM Abstract, National Meeting, May 1979.
28. D.P. Brunner, R.A. Caputo, G.S. Graham and R.W. Treick
Functional Reconstitution of Biological Properties of the Outer Membrane of Gram-Negative Bacteria (Endotoxin). Journal of Bacteriology, November 1978.
29. R.A. Caputo
Biovalidation of Sterilization Processes. Proceedings of the PMA Seminar Program on Validation of Sterile Manufacturing Processes. March 15-16, 1978.
30. D.D. Barnhart, R.A. Caputo and T.M. Petro

Primary Antigen Binding: Comparison of Minibeaker Rapid Dialysis. Equilibrium Dialysis and Ammonium Sulfate Precipitation. Journal of Immunological Methods, 1978.

31. D.P. Brunner, R.A. Caputo and R.W. Treick
Functional Reconstitution of EDTA-Treated Escherichia Coli. Biochemical and Biophysical Research Communications, February 1977.
32. R.A. Caputo, D.D. Barnhart and R.W. Treick
A Rapid Measure of Primary Antigen Binding Capacity of Antiserum. Microchemical Journal 21, 85-91, 1976.
33. R.A. Caputo, R.W. Treick, C.C. Griffin and M.P. Farrel
Rapid Determination of Cetylpyridnium Chloride Bound by Bacteria. Applied Microbiology 29, 4776-479, 1975.
34. Doctoral Dissertation: Physio-Chemical Properties and Functional Role of EDTA Released Material of Mutants of Escherichia Coli K-12. Page 678, Miami University, Oxford, Ohio, 1976.
35. Master Thesis: The Sensitivity of Escherichia Coli K-12, p. 678 Mutants to Several Commercially Utilized Antimicrobial Compounds. Miami University, Oxford, Ohio, 1974.

Presentations

- International Association of Central Supply Managers: Sterilization in the 90's, Portland, OR. May 30, 1996.
- Straub Hospital: Infection Control in The Next Century, Honolulu, Hawaii. March 29, 1996.
- Association of Operating Room Nurses: State of Sterilization Processing. March 1 – 8, 1995.
- Robertson Stephenson Investment Emerging Medical Technologies Summit: Management of High Growth Companies, November 28 – 29, 1995.
- Canadian Standard Association: Sterilization Management, Toronto, Canada, September/October 1994.
- Telemedicine Canada: The New Plazlyte™ Sterilization System, Mundelein, IL. September 29, 1993.
- Good Manufacturing Practice for the Pharmaceutical and Medical Device Industries, Amsterdam. October 12-14, 1992.
- Industrial Sterilization and Microbiological Quality Control: Sterilization Methods and Validation Procedures. Institute for Applied Technology, San Francisco, California, January 30-February 1, 1991.
- Viable Industrial Sterilization Methods of the 1990's: Gas Plasma Sterilization. Medical Device and Diagnostic Industry Conference, Anaheim, California, January 21-24, 1991.
- The Second Wave of Silicon Valley Biomedical Opportunities, Northern California Venture Capitalists, Palo Alto, California, May 16, 1990.
- Sterilization with Gas Plasma, PDA Midwest Meeting at Northbrook, Illinois, February 1990.
- Monoclonal Antibodies-Hybridoma Technology: What are the Quality Assurance Implications? Southern California ASM: San Diego, 1982.
- Cycle Development-Microbial Challenge Testing, Pilot Studies: Overkill and Bioburden Concepts. Seventh Annual AAMI/FDA Conference on Medical Device Regulation Industrial Ethylene Oxide Sterilization of Medical Devices-Process Design, Validation and Routine Sterilization. Washington D.C., December 1-3, 1980.

- Design and Use of Biological Indicators for Sterilization Cycle Validation. PMA seminar on Validation of Sterile Manufacturing Processes Biological Indicators. Chicago, Illinois, February 25-27, 1980.
- Biovalidation of Sterilization Processes. PMA seminar on Validation of Sterile Manufacturing Processes. Reston, Virginia, March 15-16, 1978.
- Primary Antigen Binding: Comparison of Minibeaker Rapid Dialysis, Equilibrium Dialysis and Ammonium Sulfate Precipitation. Indiana and Ohio Branch ASM Meeting at Eli Lilly and Company, Indianapolis, Indiana, October 1976.
- Evidence for the Functional Reconstitution of the Permeability Barrier of Escherichia Coli with EDTA-Released Material. Indiana and Ohio Branch ASM Meeting at Eli Lilly and Company, Indianapolis, Indiana. October 1976.
- A Rapid Measure of Primary Antigen Binding Capacity of Antiserum. ASM Ohio Branch Meeting at Case Western Reserve University, Cleveland, Ohio. November 1975.
- Rapid Determination of the Amount of Drug Bound by Bacteria. ASM Regional Meeting at the University of Louisville, Louisville, KY. October 1974.

ATTACHMENT 5

PURCHASE ORDER RECEIPT - NIST

amazon.com

Details for Order #111-0676813-0610651

Print this page for your records.

Order Placed: April 7, 2019
Amazon.com order number: 111-0676813-0610651
Order Total: $101.11

Preparing for Shipment

Items Ordered	Price
1 of: *Thomas Traceable Long Stem Digital Thermometer, with 3/8" High LCD Display, 8" Stem, + or - 0.2 degree accuracy, -58 to 302 degree F, -50 to 150 degree C* Sold by: Amazon.com Services, Inc Condition: New	$57.46

Shipping Address:
Jerry Igbinovia
3200 SOARING GULLS DR STE 101
LAS VEGAS, NV 89129-2198
United States

Shipping Speed:
One-Day Shipping

Item(s) Subtotal:	$57.46
Shipping & Handling:	$0.00
Total before tax:	$57.46
Sales Tax:	$4.74
Total for This Shipment:	**$62.20**

Shipped on April 7, 2019

Items Ordered	Price
1 of: *Thomas Traceable Flip-Stick Thermometer, 4.5" Stem, -58 to 572 degree F, -50 to 300 degree C* Sold by: Amazon.com Services, Inc Condition: New	$35.94

Shipping Address:
Jerry Igbinovia
3200 SOARING GULLS DR STE 101
LAS VEGAS, NV 89129-2198
United States

Shipping Speed:
One-Day Shipping

Item(s) Subtotal:	$35.94
Shipping & Handling:	$0.00
Total before tax:	$35.94
Sales Tax:	$2.97
Total for This Shipment:	**$38.91**

Payment information

Payment Method:
Visa | Last digits: 8681

Billing address
Jerry Igbinovia
3200 SOARING GULLS DR STE 101
LAS VEGAS, NV 89129-2198
United States

Item(s) Subtotal:	$93.40
Shipping & Handling:	$0.00
Total before tax:	$93.40
Estimated tax to be collected:	$7.71
Grand Total:	**$101.11**

ATTACHMENT 6

CEM SMOKE STUDY – WORK ORDER

Testing Next Week

Cari Martin <cmartin@cemanage.com>

Wed 4/3/2019 11:09 AM

To: jerry acrxpharmacy.com <jerry@acrxpharmacy.com>
Cc: Jeff Raposa <jraposa@cemanage.com>; Malica Brendle <mbrendle@cemanage.com>

Hi Jerry,

I'm following up regarding the conversation you and Jeff had yesterday about some additional testing to be scheduled next week. I can have a technician out on Thursday, April 11th around 8:00-8:30 AM, would that work for you as well?

We will plan to calibrate the 2 gauges as well as perform videotaped vapor profiles on the laminar flow hood and two powder hoods under static and dynamic conditions.

Thanks,

Cari Martin, M.S.
Field Operations Coordinator
Controlled Environment Management (CEM)
(480) 836-4144, ext. 104 Office
(480) 836-7032 Fax
[www.cemanage.com]www.cemanage.com

ATTACHMENT 7

NON-STERILE TSB MEDIA DOC

PCCA
9901 S Wilcrest
Houston, TX 77099
CA DEA#:RP0111803
Sold To: 00015548

Shipper ID :6947103
Page : 1
Sales Order:2486411

Ship To: 15548-2

*** PACKING SLIP ONLY ***

ACRX Specialty Pharmacy
Jerry Igbinovia
3200 Soaring Gulls Dr.
Suite 101
Las Vegas, NV 89129
United States of America

ACRX Specialty Pharmacy
Jerry Igbinovia
3200 Soaring Gulls Dr.
Suite 101
Las Vegas, NV 89129
United States of America

6947103

Dea # FA6553108

Ship Date	Ship Via	FOB	Terms	End Cust PO	CAC	Entered by
04/08/19	WCL		10th of ev			akochins

Ordered	Shipped	UM	Item Number	Lot	Price	Ext Price
1.00	1.00	GM	30-3585-18 SOYBEAN CASEIN DIG	C191215 Exp:02/28/23	33.49	33.49
				Product Total:		33.49

Thank you Jerry-Andres
Jerry is aware order was placed for Will Call pick up today-Andres

ST
4/9/19

QC/SHIPPER: gparkiso _____/_____ BOX _____
GND _____ 3RD _____ 2ND _____ 1ST _____ Tracking 6947103

Thank You for being a PCCA Silver member.

ATTACHMENT 8

TRAINING CONFIRMATION – LINKING OF PATIENT PRESCRIPTION MEMO

ACRX Specialty Pharmacy

Lot Linking Training

On 03/11/2019, I received training on ACRX Specialty Pharmacy's software systems 1) the Compounder and 2) Win Rx; specifically linking lot numbers to patient prescriptions prior to the medication being dispensed. This training included the following information:

- using the PK "the Compounder" software to keep track of compounding logs and master formulation records;
- using WIN Rx as the dispensing system;
- correctly documenting lot information in the pk "compounder system" and entering lot numbers into the dispensing software that are linked to patient prescription information as required;
- how to audit prescriptions at random to ensure that they appropriately linked to lot number;
- following the policy and procedures to accurately and effectively document required information needed;

With my signature and date below, I affirm that I received the training regarding lot linking procedures, and I understand and will follow the procedures outlined in this training for proper linking of patient's prescriptions to lot numbers prior to the medication being dispensed.

Print Name: Stephanie Velasquez Date: 3.11.19
Signature: S. Velasquez

Print Name: Solmaz Hashemi Date: 3.11.19
Signature:

Print Name: _____ Date: _____
Signature: _____

Print Name: _____ Date: _____
Signature: _____

Print Name: _____ Date: _____
Signature: _____

Print Name: _____ Date: _____
Signature: _____

Print Name: _____ Date: _____
Signature: _____

ATTACHMENT 9

TRAINING CONFIRMATION – COMPLAINTS HANDLING

ACRX Specialty Pharmacy

Complaint Handling Training

On April 05, 2019, I received training on ACRX Specialty Pharmacy's Complaint Handling Procedure, this training included:

- what a complaint is and who can file a complaint at ACRX Specialty Pharmacy;
- the required information for filing a complaint at ACRX Specialty Pharmacy;
- the proper documentation for filing a complaint at ACRX Specialty Pharmacy;
- the appropriate steps to report a complaint at ACRX Specialty Pharmacy;
- the immediate report to the Pharmacist in Charge (PIC) for appropriate action;
- the follow up procedure and time lines in place to accurately document a complaint filed at ACRX Specialty Pharmacy.

With my signature and date below, I affirm that I received the training regarding complaint handling procedures, and I understand and will follow the procedures outlined in this training for proper complaint handling at ACRX Specialty Pharmacy.

Print Name: Solmaz Hashemidahaj Date: 4/5/19
Signature: _____

Print Name: Stephanie Sherwood Date: 4.5.19
Signature: _____

Print Name: _____ Date: _____
Signature: _____

Print Name: _____ Date: _____
Signature: _____

Print Name: _____ Date: _____
Signature: _____

Print Name: _____ Date: _____
Signature: _____

Print Name: _____ Date: _____
Signature: _____

5E