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<td>639.955 Penalty for failing to transmit information required by NAC 639.926</td>
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TEMPORARY LICENSES
(Issued since last board meeting)

Renown Health

Jeffrey Bonner
Dzuan Nguyen

Valley Medical Center

Edna Cheung
February 4, 2016

Via Electronic Email

Dr. Larry Pinson, Executive Secretary
Nevada State Board of Pharmacy
lpinson@pharmacy.nv.gov

Re: Attorney General’s Substance Abuse Working Group

Dear Dr. Pinson:

This letter invites you to serve for a period of two years as one of nine members of the Attorney General’s Substance Abuse Working Group (July 1, 2015 through June 30, 2017). The Substance Abuse Working Group was slated to sunset, but S.B. 60 from the last legislative session extended the group through June 30, 2019.

As the recent growing heroin epidemic shows, the problem of drugs is an issue that still affects communities and families across our state and nation. I hope to partner with you to help find solutions to tackle substance abuse in our state, and know the working group will accomplish great things.

Please contact my assistant, Michele Smaltz, at msmaltz@ag.nv.gov, to confirm whether you are willing to be appointed to this important committee.

Thank you again for your consideration of this request.

Sincerely,

ADAM PAUL LAXALT
Attorney General
January 15, 2016

Larry L. Pinson  
Executive Secretary  
Nevada State Board of Pharmacy  
431 W. Plumb Ln.  
Reno, NV 89509

Re: Compounded and Repackaged Medications for Office-use

Dear Larry L. Pinson:

Our organizations represent physicians, pharmacists, other healthcare providers, surgical centers, and patient advocates treating and providing care to patients with an array of conditions requiring a broad spectrum of treatments and also pharmacists that provide physicians, hospitals, and other health care professionals with compounded medications for administration to and treatment of patients within these practice settings (often called “office-use”). As such, we have been closely monitoring the Food and Drug Administration’s (FDA) implementation of the Drug Quality and Security Act (“DQSA”, P.L. 113-54) and remain concerned about the impact of the Agency’s actions on patient access to compounded medications.

Specifically, we are deeply concerned about the implementation of the DQSA in regards to both compounded and repackaged medications for office-use. Recent implementation actions by the FDA and the information being provided by the Agency to States have caused confusion amongst State boards of medicine and pharmacy and have adversely impacted practitioner and patient access to vital medications.

Many medical professionals and healthcare facilities rely on various types of repackaged and compounded medications to treat their patients -- whether it is in their office, on a crash cart in an emergency department, or in another medical setting. These medications are essential for emergency situations as well as to initiate treatment immediately in response to a medical condition. Medications, including some biologics, are compounded or repackaged in order to meet specific dosage needs and are critical to the timely treatment of many patients when a prescriber determines that a FDA-approved drug product is neither available nor appropriate to treat their condition and achieve the best possible therapeutic outcome.

Currently, the majority of States provide for means by which prescribers may obtain both finished manufactured drug products and compounded preparations for the administration to or treatment of patients within their practice settings. When Congress re-enacted 503A within the DQSA, numerous Statements of the Record conveyed the intent that nothing within 503A was to intrude upon existing and well-established practices nor to circumvent the authority of individual
States to regulate the practice of medicine and pharmacy within their borders. Additionally, while Congress could have explicitly prohibited the compounding of medications for office-use, it did not. Despite this clear Congressional intent, FDA has conveyed a mixed message of whether office-use compounding is allowed.

Maintaining access to essential repackaged and compounded medications for office-use is not only vital for patients, but is consistent with the legislative intent of the DQSA.\textsuperscript{262,263} While reinforcing Section 503A of the Food, Drug and Cosmetic Act (FDCA) through the passage of the DQSA, Congress came together in a bipartisan and bicameral fashion to make clear that pharmacists' ability to provide compounded medications for a prescriber's administration to or treatment of a patient within their practice should be left to the States -- office-use of compounded medications is currently regulated under state law.\textsuperscript{264}

As with office-use, the DQSA did nothing to limit repackaging, and Congressional intent was that FDA would continue to allow the practice of repackaging of medications.\textsuperscript{265} Actions by FDA to limit access to repackaged medications, either by requiring a patient-specific prescription in all cases or by not allowing pharmacists to engage in repackaging, would have significant consequences for patients who rely on these therapies.\textsuperscript{266} As the DQSA did not explicitly provide for repackaging by either 503A pharmacies or the newly-created 503B outsourcing facilities, physicians and patients are now forced to rely on the FDA for issuance of further guidance on this issue.

Congress' multiple statements in the \textit{Congressional Record} show clear and overwhelming intent that compounded preparations for office-use remain available after the passage of the DQSA. These numerous statements as well as the strong urging from physician and pharmacy stakeholders, directed the agency to not limit office-use medication preparation by 503A compounders. In addition, when FDA considered changes to the Compliance Policy Guide


(CPG) for human compounding several years ago, the draft CPG specifically provided for office-use compounding.\textsuperscript{267}\n
Despite these statements and its own draft guidance, FDA stated in a September 15, 2014 response to a bipartisan letter from Congress that in order to comply with 503A, a compounding pharmacist or physician may not dispense compounded medications for office-use, but rather, must obtain or issue a prescription for an individually identified patient.\textsuperscript{268} As a result of these misleading statements by FDA, many States may have taken recent action related to office-use compounding.

The actions by FDA to prohibit all office-use compounding may result in drastically reducing patient access to vital medications. There are numerous examples of medications that 503A traditional compounders currently supply for office-use in quantities that are too small or limited to justify preparation and distribution by a 503B outsourcing facility.\textsuperscript{269}

It is also important to recognize that at the present time, the only compounded preparations a 503B outsourcing facility may compound and distribute using bulk ingredients are those products which appear on the FDA shortage list. Until such time as the Pharmacy Compounding Advisory Committee completes its review of bulk ingredients submitted for use by 503B outsourcing facilities, very few of these medications will be legally allowed to be compounded and distributed by them.

Congress disagrees strongly with FDA’s statements that the DQSA prohibits compounding and repackaging for office-use. In addition to the statements in the Congressional record and letters from key Members of Congress to the Agency, Congress has included in the House Report 114-2015 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill, 2016 language that states its concerns with FDA’s interpretation of section 503A on office use that is inconsistent with the legislative intent of the DQSA and even the agency’s own previous positions on office use compounding.

This past week, Congress approved House Report 114-2015. Within that, the Agency has now been directed to issue guidance which specifically addresses how office-use compounding will be permitted. That guidance must be issued within 90 days of the final enactment of the report.

Specifically, the language which will directly impact your Board’s regulatory and rule-making activities related to office-use compounding is as follows:

\textit{Drug Compounding} -- The Committee is concerned that, since passage of the Drug Quality and Security Act (DQSA) of 2013, the FDA has interpreted provisions of Section 503A of the FDCA in a manner inconsistent with its legislative intent and with the


\textsuperscript{269} See Appendix A for a compiled list of examples of medications supplied for office-use.
agency's own previous positions. Specifically, the FDA has taken the position that under 503A, a pharmacist may not compound medications prior to receipt of a prescription and transfer the drugs to a requesting physician or other authorized agent of the prescriber for administration to his or her patients without a patient-specific prescription accompanying the medication. This practice, which is often referred to as 'office-use' compounding, is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee is aware that in 2012, prior to passage of the DQSA, FDA was working on a draft compliance policy guide for 503A of the FDCA that provided guidance on how 'office-use' compounding could be done consistent with the provisions of 503A. The Committee understands the intent of the DQSA was not to prohibit compounding pharmacists from operation under existing 503A exemptions; therefore, the Committee directs the FDA to issue a guidance document on how compounding pharmacists can continue to engage in 'office-use' compounding before the receipt of a patient-specific prescription consistent with the provisions of 503A within 90 days after the enactment of this Act. (emphasis added).270

Our organizations urge the members of your Board to delay consideration of any pending regulatory or policy decisions on the ability of practitioners to obtain and use office-use compounded preparations until such time as the Agency issues its guidance in a manner that is consistent with this new Congressional directive. Additionally, given that FDA's previous position and information which may have been provided to your Board by the Agency may have been contradictory to Congress's intent, we urge you to review and potentially reconsider any recent decisions to prevent, eliminate or restrict office-use compounding within your State.

Sincerely,

Alaska Pharmacists Association (AKPhA)
Alabama Pharmacy Association (APA)
Alliance for Natural Health USA (ANH-USA)
Alliance of Independent Pharmacists of Texas
Ambulatory Surgery Center Association (ASCA)
American Academy of Dermatology Association (AADA)
American Academy of Ophthalmology (AAO)
American Association of Naturopathic Physicians (AANP)
American Pharmacists Association (APhA)
American Society of Cataract and Refractive Surgery (ASCRS)
American Society of Consultant Pharmacists (ASCP)
Arizona Pharmacy Association (AzPA)
Arkansas Pharmacists Association (APA)
California Pharmacists Association (CPhA)
Illinois Pharmacists Association (IPhA)
International Academy of Compounding Pharmacists (IACP)
Michigan Pharmacists Association (MPA)

Minnesota Pharmacists Association (MPhA)
Missouri Pharmacy Association (MPA)
National Alliance of State Pharmacy Associations (NASPA)
National Community Pharmacists Association (NCPA)
Nebraska Pharmacists Association (NPA)
New Hampshire Pharmacists Association (NHPA)
New Jersey Pharmacists Association (NJPhA)
New Mexico Pharmacists Association (NMPhA)
North Carolina Association of Pharmacists (NCAP)
PCCA
Pennsylvania Pharmacists Association (PPA)
South Carolina Pharmacy Association (SCPhA)
South Dakota Pharmacists Association (SDPhA)
Tennessee Pharmacists Association (TPA)
The Ohio Pharmacists Association (OPA)
Virginia Pharmacists Association (VPhA)
Washington State Pharmacy Association (WSPA)
The following are some examples of the medications that 503A traditional compounders currently supply for office-use in quantities that are too small or limited to justify preparation and distribution by a 503B outsourcing facility:

- Topical Phenol used by podiatrists and primary care physicians to treat in-grown toenails.
- Topical cantharidin (one strength is 52.5 mg / ml [0.7%]) used by podiatrists, primary care physicians, and dermatologists for the treatment of warts.
- Topical podophyline used by podiatrists, primary care physicians, and OB/GYNs.
- Topical Diphenylcypropenone in many strengths compounded from raw material and acne for use by dermatologists treating alopecia areata.
- Topical Squaric acid for use by dermatologists in treating alopecia areata.
- Bleaching gels of various formulas used by dentists in teeth whitening procedures.
- Glycolic acid solutions used by dermatologists in skin peel procedures.
- Trichloroacetic acid solutions used by dermatologists in skin peel procedures.
- Lidocaine, Epinephrine, and Tetracaine (LET or LAT) gel/solution and derivatives used by ERs and Primary Care Physicians as a local anesthetic used to decrease pain while suturing patients – especially pediatric patients.
- Dextrose capsules #0, 00, 000, 1, 2, 3, and 4 for use by Social Work to teach pediatric patients how to swallow capsules.
- Tamsulosin 0.2 mg capsules (open up the 0.4 mg capsules, weigh total contents then weigh in half, pack into #4 capsules) used off-label for kidney stones in pediatric patients.
- Various powder-filled capsules - many formulations out in the industry with mixtures of 3-4 ingredients that may include ciprofloxacin, amphotericin, dexamethasone, clotrimazole, and lidocaine and others for use in Sheehy-House powder insufflators for insertion into the ear to treat refractory external ear infections.
- Topical Sodium Nitrate solution used in labs for diagnosis of cystic fibrosis via sweat testing.
- Topical Pilocarpine Nitrate solution used in labs for diagnosis of cystic fibrosis via sweat testing.
- Hydroxyzine pamoate suspension for use by pediatric dentists for mild sedation
- Combination antibiotic eye drop used by ophthalmology surgery centers.
- EDTA ophthalmic eye drops for surgery
- Bevacizamab (Avastin) repack used by ophthalmology clinics for treatment of wet macular degeneration.
- Alteplase 1 mg / ml syringes when commercial vials are on backorder and shortage from manufacturers.
- Oxymetazoline Nasal Spray + Lidocaine 4% injection compounded 1:1 in an ISO 5 environment and packaged into sterile oral syringes for storage in automated dispensing cabinets for ENT to use with an automizer prior to exam in office.
- Surgical Irrigations
- Bacitracin 50,000 units in 0.9% nacl 3000 ml (bag).
- Bacitracin 50,000 units in 0.9% nacl 1000 ml (bag or bottle).
- Bacitracin 25,000 units in 0.9% nacl 500 ml (bottle).
- Bacitracin, Gentamicin and Cefazolin in 0.9% nacl 500 ml or 1000 ml (bottle).
- **Organ Transplant Irrigations, Soaks and Baths**
  - Cardioplegia solutions (mixtures of lidocaine, electrolytes, mannitol, dextrose, etc.).
  - Epinephrine in 0.9% nacl (bottle).
  - Phenylephrine in 0.9% nacl (bag).
- **Crash/Emergency Cart drugs/ICU/Ambulance/Helicopter/Airplane**
  - Phenylephrine syringes used for Anesthesia/ER crash carts, concentrations of 50 and 100 mcg / ml that are not commercially available; there is chronic backorder and shortage from manufacturers of vials 10 mg / ml to even compound the 50 and 100 mcg / ml syringes.
  - Sodium Bicarbonate used by Anesthesia/ER crash carts, a sterile drug that has been on chronic backorder and shortage from manufacturers.
  - Calcium Chloride used by Anesthesia/ER crash carts/dialysis centers – chronic backorder from manufacturers.
  - Calcium Gluconate used by icus /dialysis centers; chronic backorder from manufacturers.
  - Narcotic drug syringes; fentanyl, sufentanil used for anesthesia in outpatient surgery centers and physician offices.
  - Propofol repackaged into 10 and 20 ml syringes during shortages.
  - Dexametomidine straight from diluted commercial vial or compounded with 0.9% NS and concentrated vial, then packaged in syringes.
  - Heparin 500 units / ml (3 ml) compounded then packaged in syringes for dialysis.
  - Heparin 2,000 units / ml (3 ml) compounded then packaged in syringes for dialysis.
  - Heparin 1,000 units / ml (3 and 8 ml) packaged in syringes for dialysis.
  - Lidocaine 1% buffered with nabicarb (0.8 & 5 ml) packaged in syringes for IV starts and dialysis.
  - Lidocaine with nabigarb (0.2 ml) packaged in J-tip syringes for IV starts and shots in ER, surgery centers, inpatient and clinics.
  - Morphine 1 mg / ml compounded using commercial product and 0.9% nacl (1 ml) syringe for storage in automated dispensing cabinets, and anestheis carts
  - Hydromorphone 0.2 mg / ml for PCA (50 ml) syringe for storage in automated dispensing cabinets within health systems and long term care facilities.
  - Hydromorphone 1 mg / ml for PCA (50 ml) syringe for storage in automated dispensing cabinets within health systems and long term care facilities.
  - Methadone 1 mg / ml compound from commercial product and 0.9% nacl (1 ml) syringe for storage in automated dispensing cabinets within health systems and long term care facilities.
- Morphine 2 mg / ml for PCA (25 ml) syringe prepared from commercial product and 0.9% NaCl for storage in automated dispensing cabinets within health systems and long term care facilities.
- Fentanyl 10 mcg / ml NEONATAL (1 and 10 ml) compounded from commercial product and 0.9% NaCl and packaged in bar-coded syringes for storage in automated dispensing cabinets within health systems and long term care facilities.
- Heparin 2 units / ml compounded from Heparin and 0.45% NaCl commercial products (250, 500 and 1000 ml bags) for storage in automated dispensing cabinets within health systems and long term care facilities.
- Epinephrine 0.01 mg / ml compounded from epinephrine and D5W commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
- Epinephrine 0.02 mg / ml compounded from epinephrine and D5W commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
- Nicardipine 0.5 mg / ml compounded from Nicardipine and D5W commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
- Nicardipine 0.5 mg / ml compounded from Nicardipine and 0.9% NaCl commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
- Dextrose 10% plus 14.5% NaCl or 23.4% NaCl to prepare D10 and NaCl 0.2% (250 ml) bag due to commercial product on chronic mfg b/o (prepared from commercial products).
- Dextrose 10% plus 14.6% NaCl or 23.4% NaCl plus heparin to equal 1 unit / ml to prepare D10 and NaCl 0.2% and Heparin 1 unit / ml (250 ml) bag (prepared from commercial products) may be stored in automated dispensing cabinets.
- Bupivacaine 0.25 % + Epinephrine = 1:200,000 injection for use in surgery and surgery centers.
- Epinephrine 1:100,000 injection prepared from epinephrine and 0.9% NaCl commercial products for use in surgery and surgery centers.
- Epinephrine 1:400,000 injection prepared from epinephrine and 0.9% NaCl commercial products for use in surgery and surgery centers.
- Lidocaine 0.25% with Epinephrine 1:400,000 units injection prepared from commercial products in a vial for use in surgery and surgery centers.
- Lidocaine 1% with Epinephrine 1:10,000 units injection prepared from commercial products into a vial for use in surgery and surgery centers.
- Ropivacaine 0.2% with Epinephrine 1:200,000 units injection prepared from commercial products into a vial for use in surgery and surgery centers.
- Milrinone 0.2 mg / ml compounded or premix commercial product repackaged into 20 and 50 ml syringes for storage in automated dispensing cabinets.
- Pentobarbital 50 mg / ml commercial product repackaged into 1 ml syringe for cath lab and anesthesia surgery centers.
- Methadone 5 mg / 0.5 ml commercial product repackaged from large commercial vial into 0.5 ml syringes for storage in automated dispensing cabinets.
- Dopamine 1.6 and 3.2 mg/ml compounded or premix commercial product repackage into 20 and 50 ml syringes for each for storage in automated dispensing cabinets.
- Nitroglycerin 0.4 mg/ml commercial product repackage into 20 and 50 ml syringes during commercial product manufacturing back order and shortages.
- Fentanyl 50 mcg/ml injection repackage from commercial product into 8, 24 and 50 ml syringes maybe stored in automated dispensing cabinets.
- Iopamidol (Isovue) 61% injection repackage into 20 ml syringes during manufacturing back order and shortages.
- Botulinium Toxin solution reconstituted commercial product and packaged in syringes for office use treatment of spasticity, diagnosis of gastrointestinal disorders and which dermatologists and plastic surgeons also use.
- Ceftriaxone mixed with lidocaine to 350 mg/ml, drawn up in 1.1, 1.4 and 2.2 ml volumes in an ISO 5 environment for storage in an automated dispensing cabinet refrigerator in ers and clinics.
ACTIVITIES REPORT

JANUARY 13-14, 2016 BOARD MEETING HELD IN LAS VEGAS, NEVADA

This report is prepared and presented to keep interested legislators and others abreast of the activities of the Nevada State Board of Pharmacy. Following is a summary of the January, 2016 Board meeting.

Licensing Activity:

- 59 licenses were granted for Out-of-State MDEG (Medical Devices, Equipment and Gases) companies.
- 6 licenses were granted for Nevada MDEG companies, and 1 denied pending reorganization.
- 24 licenses were granted for Out-of-State pharmacies, pending receipt of a favorable inspection for all compounding pharmacies.
- 14 licenses were granted for Out-of-State wholesalers & one was denied.
- 24 licenses were granted for Nevada pharmacies.
- 1 license was granted for a Nevada wholesaler.
- 1 license was granted for a reciprocal pharmacist after satisfactorily answering past discipline questions and another denied due to pending action in California.
- 1 license to sit for NAPLEX (Board Exam) was denied until the applicant seeks treatment for drug abuse.
- 1 license for prescriptive authority for controlled substances was granted pending enrollment in PRN-PRN (recovery program) and another granted for all schedules except schedule II due to a past criminal conviction for prescribing unlicensed.

Disciplinary Actions:

- Pharmaceutical technicians IR and LB and pharmacist AI were all revoked for diversion of controlled substances and dangerous drugs for personal use from pharmacy CV.
- Pharmacist TR was fined $750; and ordered 2 extra hours of CE for dispensing and counseling a cholesterol drug rather than an antidepressant. Pharmacist LM was ordered the same and pharmacy WG in Las Vegas was fined $495 admin fees. WG mail order was fined $1000 plus admin fees for the same offense.
- Pharmacist JC was revoked for fabricating prescriptions for himself and others to "stockpile for judgement day".
- Pharmacist JH was fined $995 and ordered 4 hours of extra CE for dispensing the wrong medication to a patient.
- MDEG VC was fined $500 plus $495 admin fees for sending out an improperly set ASV (auto servo ventilator) to a patient. The respiratory therapist (RT) who did the settings was referred to the Medical Board for discipline (his licensing board). VC was ordered to develop better policies and procedures for such activity to prevent further incidents.
Other Activity:

- The usual Board business reports were given, including recent and future speaking engagements; reports on national meetings; and collaboration with other state agencies.
- Recommendations by the Board CE Committee were approved for two CE programs.

WORKSHOP:

New Language to be added to NAC Chapter 639, pursuant to the Good Samaritan Drug Overdose Act, SB 459 (2015), establishing standardized procedures or protocols for the furnishing of opioid antagonists by pharmacists and other appropriate entities to persons at risk of experiencing an opioid-related overdose or to a family member, friend or other person in a position to assist persons at risk of experiencing an opioid-related drug overdose.

PUBLIC HEARING:

Amendment of Nevada Administrative Code (NAC) 453.540 Schedule IV
The proposed amendment will add lorcaserin to the controlled substances listed in Schedule IV, and provides for other matters properly related thereto.

Amendment of Nevada Administrative Code (NAC) 639.926 Transmission of information regarding dispensing of controlled substances to certain persons.
Amends the rule that presently establishes frequency of the controlled substance information transmitted to the Board. The amendment will improve the timeliness of the date to improve the quality of the data provided to practitioners and pharmacies pursuant to NRS 453.1545 and SB459.