Nevada State Board of Pharmacy
985 Damonte Ranch Suite 206, Reno, NV 89521
(775) 850-1440 (800)-364-2081 Fax (775) 850-1444

To: Dispensing Practitioner
FROM: Nevada State Board of Pharmacy Inspector
SUBJECT: Self-Assessment Inspection Process

The Board of Pharmacy's established self-assessment inspection process provides management the opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services. An inspection evaluation form must be obtained from the NVBOP website to self-assess compliance with Nevada pharmacy law. An inspector will review the form with you and inspect your facility during the month listed on your inspection notice. Please have the self-assessment form completed and available for review by the first day of the month listed on your inspection notice.

An inspector will conduct a review of your operation. Observations, along with your findings, will assure understanding and compliance with Nevada law.

Please attach your inspection notice that you received in the mail to your completed self-assessment inspection form.

To minimize the disruption to your facility during the inspection process please have the following documents available:

Completed inspection form along with prior year inspection form

Non-Sterile Compounding inspection form if applicable

Sterile Compounding inspection form if applicable

Completed DEA-222 and/or E-222 (CSOS) electronic forms since last inspection (if applicable)

Most recent biennial controlled substance audit (if applicable)

Nevada Law CE documents for all pharmacy technicians

List of dangerous drugs and controlled substances dispensed at facility

Perpetual inventory logs for C-II medications (if applicable)

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Drug Storage Area:

Citation	Question			
	Is the area clean and maintained in an orderly manner?	Yes	No	N/A
NRS 639.1373	Current license(s) displayed?	Yes	No	N/A
	Temperature compatible with drug storage requirements? (59-86 F)	Yes	No	N/A
NRS 639.282 NAC 639.525	Does the facility carry products required to be stored in a refrigerator prior to dispensing? (If NO skip to next section)	Yes	No	N/A
	Dedicated medication refrigerator?	Yes	No	N/A
	Is refrigerator clean?	Yes	No	N/A
	Is the temperature proper for the storage of drugs? (36 – 46 F)	Yes	No	N/A
	Is the refrigerator sufficient size?	Yes	No	N/A
	Is a daily temperature log maintained?	Yes	No	N/A

Stock of Drugs:

Citation	Question			
NRS 585.410-NRS 585.460	Are all pharmaceuticals in stock properly labeled?	Yes	No	N/A
	Name of Product?	Yes	No	N/A
	Manufacturer's Name?	Yes	No	N/A
	Lot Number?	Yes	No	N/A
	Expiration Date?	Yes	No	N/A
NRS 639.282 NAC 639.510	Are outdated, mislabeled, or adulterated drugs removed from stock and secured in an area where they will not be used to fill prescriptions?	Yes	No	N/A
	Indicate the location of all quarantined products:	_____		
NAC 639.742 (3)(g)	Is the price of each drug dispensed separately itemized on any bill or statement provided to the patient?	Yes	No	N/A

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Containers and Labeling:

Citation	Question			
NAC 639.740	Are prescribed medications dispensed in a container which is designed to prevent a child from opening it?	Yes	No	N/A
NRS 639.2801	Is each prescription container properly labeled with the following information:			
	The date filled?	Yes	No	N/A
	The name of the dispensing practitioner?	Yes	No	N/A
	Name of the patient?	Yes	No	N/A
	Specific directions for use?	Yes	No	N/A
	Expiration date of the drug?	Yes	No	N/A
	Name, strength, & quantity of drug dispensed?	Yes	No	N/A
	Alcohol/non-prescribed drug warning?	Yes	No	N/A
	Prescription number/Serial number?	Yes	No	N/A
	Is label affixed to immediate container?	Yes	No	N/A
NRS 585.450 NAC 453.470	Proper warning labels attached?	Yes	No	N/A
	Does the facility dispense products requiring reconstitution?	Yes	No	N/A
	If yes, are there adequate graduates for measuring?	Yes	No	N/A

Records:

Citation	Question			
	Prescriptions are (circle)	electronic	handwritten	
NRS 454.223	Prescriptions contain the following:			
	Name of patient and address if not immediately available to the practitioner?	Yes	No	N/A
	Name/strength/quantity of drug prescribed?	Yes	No	N/A
	Name of the practitioner and class of his/her license?	Yes	No	N/A
	Practitioner's DEA number if the prescribed drug is a CS?	Yes	No	N/A
NAC 639.751	The initials of the dispensing practitioner involved in the preparation of the prescription dispensing?	Yes	No	N/A
NAC 639.751	The initials of the dispensing technician if involved in the preparation of the prescription dispensing?	Yes	No	N/A
	The signature of the prescribing practitioner?	Yes	No	N/A
	The directions for use?	Yes	No	N/A

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Records:

Citation	Question			
	How does the facility file completed prescriptions (circle)	electronic	paper file	
NAC 639.280 NAC 639.743 NAC 639.879	Does the practitioner and dispensing technician or trainee initial and date the prescription and initial the prescription label after filling?	Yes	No	N/A
NAC 639.742 (3)(a)	Are all drugs ordered by the dispensing practitioner?	Yes	No	N/A
NAC 639.742 (3)(b)	Are all drugs received and accounted for by the dispensing practitioner?	Yes	No	N/A
NAC 639.745	Is a patient informed consent for the practitioner to dispense the medication documented for each product dispensed?	Yes	No	N/A
NAC 639.918	Are prescriptions ever refilled using the same prescription number?	Yes	No	N/A
	If yes, is a separate drug refill log maintained?	Yes	No	N/A
	Does the practitioner maintain the dispensing records properly and retain them for 2 years?	Yes	No	N/A
	Is a daily log kept that documents which dispensing technician or trainee is assigned to each practitioner that day (ratio is 1:1)?	Yes	No	N/A
	Have all dispensing technicians completed the 1 hour of Nevada Board of Pharmacy approved Law during their 2 year registration period?	Yes	No	N/A

Controlled Substances:

Citation	Question			
	Does the facility dispense controlled substances? (if NO then skip to the next section)	Yes	No	N/A
	Does the facility dispense schedule II drugs?	Yes	No	N/A
	If yes, are schedule II prescriptions filed separately from all other prescriptions?	Yes	No	N/A

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Controlled Substances:

Citation	Question			
	Does the facility use the Controlled Substance Ordering System (CSOS) for ordering Schedule II controlled substances?	Yes	No	N/A
	If yes, is the CSOS receiving document printed and attached to the invoice from the wholesaler?	Yes	No	N/A
21 CFR 1305.06	Are schedule II order forms properly completed?	Yes	No	N/A
NAC 453.410	Are schedule II invoices filed separately from all other invoices?	Yes	No	N/A
NAC 639.485	Is a perpetual inventory completed for schedule II drugs?	Yes	No	N/A
	Does the facility dispense schedule III-V controlled substances?	Yes	No	N/A
NAC 453.410	Are schedule III-V invoices filed separately from all other records?	Yes	No	N/A
21 CFR 1304.11	Has a biennial inventory of controlled substances been completed?	Yes	No	N/A
	Date of most recent biennial inventory:	_____		
	Does the facility report all controlled substances dispensed daily to the Nevada controlled substance task force (PMP)?	Yes	No	N/A
	Does the facility report a zero dispensed report for each day when controlled substances are not dispensed?	Yes	No	N/A
	You are required to submit electronically, daily, data on all controlled substances dispensed to the PMP. Email: pmp@pharmacy.nv.gov. Phone: 775-687-5694			
	Has the practitioner registered to access and is the practitioner accessing the PMP as required?	Yes	No	N/A
If dispensing controlled substances:				
NRS 453.568	Has there been any theft or loss of controlled substances Since the last inspection?	Yes	No	N/A
	If yes, was a DEA-106 form completed?	Yes	No	N/A
NRS 453.568	If yes, was the theft or loss of all controlled substances properly reported to the Nevada State Board of Pharmacy within 10 days of the loss?	Yes	No	N/A
21 CFR 1307.21 NAC 639.050	Was a DEA-41 form, voluntary surrender of controlled substances, completed for any controlled substance destroyed by the practitioner?	Yes	No	N/A

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Security:

Citation	Question			
NAC 453.400 NAC 639.285 NAC 639.898 NAC 639.520	Are controlled substances/dangerous drugs kept in a deadbolt locked storage area?	Yes	No	N/A
NAC 639.743	Are licensed practitioners the only person(s) with possession of a key?	Yes	No	N/A
	Does the facility have an alarm system?	Yes	No	N/A
	Name of alarm system provider: _____			

Management:

Citation	Question			
	Does the practitioner understand he/she is legally responsible for The dispensing process?	Yes	No	N/A
NRS 639.282	Are prescription drugs, previously dispensed to consumers, accepted for return?	Yes	No	N/A
	Is the facility contracted with a vendor to supply computer software or pharmaceutical products?	Yes	No	N/A
	Computer software vendor: _____			
	Pharmaceutical vendor: _____			

Purchasing:

Citation	Question			
NAC 639.757	Are you purchasing for sale or dispensing to your patients from only Nevada licensed manufacturer of pharmaceutical products or a Nevada licensed wholesaler?	Yes	No	N/A
	If purchasing compounded product is the product only administered to patients at your facility?	Yes	No	N/A

If you are purchasing commercially available (manufactured and FDA approved) products to dispense please confirm that the product's provider is licensed to sell product in Nevada by checking the NVBOP website.

A pharmacy is not allowed to compound a product for sale to a practitioner for the purpose of resale by the practitioner.

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List of wholesalers/manufacturers utilized by dispensing practitioner:

_____

_____

_____

Remarks/Suggestions/Comments/Follow-up Information:

Inspector Use Only

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If you are required to provide any documentation to the inspector via fax or e-mail please attach a copy of the documents to this inspection form for future review on inspection.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

Please fax required documents to 1-775-850-1444 for Reno inspectors

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

I acknowledge that any noted unsatisfactory conditions have been explained to me and that I have received a copy of this inspection report.

Dispensing Practitioner signature: _____

Dispensing Practitioner name: _____

Date: _____

Dispensing Practitioner signature: _____

Dispensing Practitioner name: _____

Date: _____

NVBOP Inspector signature: _____

NVBOP Inspector printed name: _____

Date: _____

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Dispensing Practitioner Guidelines

Listed below are some of the more common regulatory requirements pertaining to practitioner dispensing practices that you might find helpful. We recommend reviewing this information upon applying for a dispensing practitioner license and annually thereafter. In addition to the bullet points listed below we have included some of the specific law citations if you would like to review these in more detail. This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

A dispensing practitioner:

- Shall order all drugs;
- Shall receive and account for all drugs;
- Shall have their own inventory this is secured in a locked room or cabinet to which the
- practitioner has the only key or lock combination;
- Shall have a bona fide relationship with his/her patient;
- Shall only dispense medications the practitioner prescribes. The practitioner shall not dispense medications prescribed by another practitioner;
- Shall ensure that no drug may be dispensed without the practitioner on-site at the facility;
- Shall ensure that all drugs are dispensed personally to the patient at the facility; medications dispensed cannot be mailed;
- The practitioner and, if applicable, the dispensing technician or trainee shall initial both the prescription label and the prescription record;
- Shall ensure that all drugs are dispensed in compliance with NAC 639.745;
- Shall inform the patient that the patient may request a written prescription and have it filled at a pharmacy of their choice;
- The informed consent for each prescription must be initialed and dated by the patient and kept with the prescription record;
- Shall write a prescription for any medication the practitioner will dispense to a patient, and keep a record of all medications dispensed.
- Shall separately itemize the drug price of each drug dispensed on any bill or statement provided to the patient;
- If the practitioner intends to dispense controlled substances, an initial inventory and a biennial inventory must be taken;
- A perpetual inventory must be kept for all schedule II controlled substances;
- The practitioner must report daily the dispensing of controlled substances daily to the Nevada Prescription Monitoring program (PMP), even if there are no controlled substances dispensed;
- SB459 sets the criteria requiring when a practitioner must access the PMP and requires accessing the PMP to check a patient's history of controlled substances they have received previously if the criteria are met;

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Citations from the Nevada Administrative Code

NAC 639.742 Dispensing of controlled substances or dangerous drugs: Application by practitioner for certificate of registration; application by facility required under certain circumstances; duties of dispensing practitioner and facility relating to drugs; authority of dispensing practitioner and technician. (NRS 639.070**,** 639.0727**)**

1. Except as otherwise provided in NAC 639.7423, a practitioner who wishes to dispense controlled substances or dangerous drugs must apply to the Board on an application provided by the Board for a certificate of registration to dispense controlled substances or dangerous drugs. A practitioner must submit a separate application for each site of practice, including, without limitation, a telepharmacy, remote site or satellite consultation site, from which the practitioner wishes to dispense controlled substances or dangerous drugs. A certificate of registration to dispense controlled substances or dangerous drugs is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.

2. Except as otherwise provided in NAC 639.7423, if a facility from which the practitioner intends to dispense dangerous drugs or controlled substances is not wholly owned and operated by the practitioner, the owner or owners of the facility must also submit an application to the Board on a form provided by the Board.

3. Except as otherwise provided in NRS 639.23277 and NAC 639.395, 639.648 and 639.7423, the dispensing practitioner and, if applicable, the owner or owners of the facility, shall ensure that:

(a) All drugs are ordered by the dispensing practitioner;

(b) All drugs are received and accounted for by the dispensing practitioner;

(c) All drugs are stored in a secure, locked room or cabinet to which the dispensing practitioner has the only key or lock combination;

(d) All drugs are dispensed in accordance with NAC 639.745;

(e) No prescription is dispensed to a patient unless the dispensing practitioner is on-site at the facility;

(f) All drugs are dispensed only to the patient personally at the facility;

(g) The price of each drug dispensed to a patient is separately itemized on any bill or statement provided to the patient;

(h) All drugs are dispensed only for medically necessary purposes and according to prevailing standards of care for practitioners practicing in the specialty claimed or practiced by the dispensing practitioner; and

(i) The certificate for each dispensing technician employed at the facility is displayed in the room or cabinet in which drugs are stored.

4. Except as otherwise provided in NAC 639.648 and 639.7423, with regard to the filling and dispensing of a prescription at a facility, only the dispensing practitioner or a dispensing technician may:

(a) Enter the room or cabinet in which drugs are stored;

(b) Remove drugs from stock;

(c) Count, pour or reconstitute drugs;

(d) Place drugs into containers;

- (e) Produce and affix appropriate labels to containers that contain or will contain drugs;

(f) Fill containers for later use in dispensing drugs; or

(g) Package or repackage drugs.

5. Except as otherwise provided in NAC 639.7423, a dispensing practitioner may compound drug products if he or she complies with the provisions of NAC 639.661 to 639.690, inclusive, as if:

(a) He or she were a pharmacist;

(b) His or her practice site was a pharmacy; and

(c) Any dispensing technician involved in the compounding was a pharmaceutical technician.

(Added to NAC by Bd. of Pharmacy by R034-02, eff. 5-30-2003; A by R035-06, 9-18-2008; R037-10, 10-15-2010; R098-13, 3-28-2014; R146-17 & R015-18, 5-16-2018)

NAC 639.745 Duties of certain practitioners concerning dispensing of controlled substances and dangerous drugs; maintenance of records. (NRS 639.070**,** 639.0727**)**

1. Except as otherwise provided in NAC 639.7423, each practitioner who is registered with the Board to dispense controlled substances and dangerous drugs, including, without limitation, a dispensing practitioner, and who dispenses such products for use by the practitioner's patients outside his or her presence shall:

(a) Keep complete, accurate and readily retrievable records of each controlled substance and dangerous drug purchased and dispensed. The record for each such product dispensed to a patient must include:

(1) The name of the patient and, if not readily available from the practitioner's records, the patient's address;

(2) The name, strength and quantity of the prescribed controlled substance or dangerous drug;

(3) The directions for use;

(4) The date the prescription was issued; and

(5) A unique identifying number.

(b) Maintain a separate file for the records concerning the purchase of each controlled substance listed in schedule II and a separate file for the records concerning the dispensing of each controlled substance listed in schedule II. Each prescription for a controlled substance or dangerous drug must be maintained in a separate file pursuant to the requirements set forth in NAC 453.480.

(c) Keep all controlled substances and dangerous drugs in a locked storage area. Access to the storage area must be restricted to the persons described in NRS 453.375.

(d) Ensure that each package or container in which a controlled substance is dispensed, except samples in the manufacturer's packages, is clearly labeled pursuant to the requirements set forth in NRS 639.2801.

(e) Ensure that the package or container in which a controlled substance or dangerous drug is dispensed complies with all state and federal packaging requirements.

(f) Be deemed to be a pharmacy as that term is used in NAC 639.926 and shall comply with that section.

2. Except as otherwise provided in NAC 639.7423, a practitioner may dispense dangerous drugs or controlled substances only after the patient has been informed by the practitioner that the patient may request a written prescription and have it filled at another location of the patient's choosing.

3. A record regarding the dispensing of a controlled substance or dangerous drug made and kept pursuant to this section must be maintained on paper or in a computer. If the record is:

(a) Maintained on paper, the record must:

(1) Include all the information required to be on the prescription pursuant to NRS 639.2353 and NAC 453.440;

(2) Set forth on the front of the prescription a certification initialed and dated by the patient that the patient has been informed by the practitioner in accordance with subsection 2 and that the patient has agreed to have the practitioner dispense the controlled substance or dangerous drug; and

(3) Be serially numbered and kept in numerical order in a single file for all dispensing practitioners, including, without limitation, physician assistants and advanced practice registered nurses, practicing at the same location.

(b) Maintained in a computer, the record must:

(1) Include all the information required to be on the prescription pursuant to NRS 639.2353 and NAC 453.440;

(2) Contain a certification, either in the computer or a separate paper document, initialed and dated by the patient that the patient has been informed by the practitioner in accordance with subsection 2 and that the patient has agreed to have the practitioner dispense the controlled substance or dangerous drug; and

(3) Be searchable for any item required by paragraph (a) of subsection 1 to be included in the record.

(Added to NAC by Bd. of Pharmacy, eff. 2-6-90; A by R034-02, 5-30-2003; R157-04, 10-22-2004; R037-10, 10-15-2010;

NAC 453.410 Dispensing of controlled substances by practitioner. (NRS 453.221**,** 453.246**,** 639.070**)**

1. A practitioner, as defined in subsections 1 and 2 of NRS 453.126, who is registered with the Board to possess and dispense controlled substances and dispenses the substances for use by the practitioner's patients outside his or her presence, shall:

(a) Keep complete, accurate and readily retrievable records of all controlled substances so dispensed. Each written prescription must be serially numbered and kept in numerical order.

(b) Ensure that each record of a controlled substance which is dispensed contains the:

(1) Name of the patient and, if not readily available from the practitioner's records, the patient's address.

(2) Name, strength and quantity of the controlled substance dispensed.

(3) Date the controlled substance was dispensed.

(4) Name of the prescribing practitioner and the classification of his or her license.

(5) Practitioner's registration number issued by the Drug Enforcement Administration of the United States Department of Justice.

(6) Initials of the dispensing practitioner, if the dispensing practitioner did not prescribe the controlled substance.

(7) Directions for use.

(8) Signature of the prescribing practitioner.

 The practitioner shall provide this information to an agent of the Board upon request.

(c) Maintain a separate file for the records concerning the purchase of each controlled substance listed in schedule II and a separate file for the records concerning the dispensing of each controlled substance listed in schedule II. Each prescription for a controlled substance or dangerous drug must be maintained in a separate file pursuant to the requirements set forth in NAC 453.480.

(d) Keep all controlled substances and dangerous drugs in a locked storage area. Access to the storage area must be restricted to the persons described in NRS 453.375.

(e) Ensure that each package or container in which a controlled substance is dispensed, except samples in the manufacturer's packages, is clearly labeled pursuant to the requirements set forth in NRS 639.2801.

(f) Ensure that the package or container in which a controlled substance or dangerous drug is dispensed complies with all state and federal packaging requirements.

2. A practitioner may dispense dangerous drugs or controlled substances to a patient only after he or she has issued a written prescription that authorizes the patient to have it filled at another location of the patient's choosing or by the dispensing practitioner.

[Bd. of Pharmacy, § 453.230, eff. 6-26-80] — (NAC A 9-29-87; 8-31-88; 2-6-90; 8-27-96)

Dispensing Site Information

Date Completed:	
Location Name:	
Location Address:	
Location Telephone Number:	
Location Fax Number:	
Location Email:	

Please fill out the below information for your Location Staff – use 2nd sheet if necessary

Position	Name (First and Last Name)	License Number
Practitioners:		
Dispensing Techs(s):		

Additional Comments: