NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

<u>Dispensing Practitioner Inspection: Instruction Sheet and Form</u> (Revised 1/2022)

The NVBOP'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.

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 review the form with you and inspect your facility during the month listed on your inspection notice.

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

- 1. Completed inspection form along with prior year inspection form
- 2. Non-sterile Compounding inspection form (if applicable) Inspection Forms (nv.gov)
- 3. Sterile Compounding inspection form (if applicable) Inspection Forms (nv.gov)
- 4. Completed DEA-222 and/or E-222 (CSOS) electronic forms since last inspection (if applicable)
- 5. Most recent biennial controlled substance audit (if applicable)
- 6. Nevada Law CE documents for all dispensing technicians
- 7. List of dangerous drugs and controlled substances dispensed at facility
- 8. Perpetual inventory logs for C-II medications (if applicable)

Dispensing Practice Information			
Date Completed:			
Location Name:			
Location License #:			
Location Address:			
Location Telephone #:			
Location Fax #:			
Location Email:			

List	List all Dispensing Practitioners – (Make copies of this page if additional space is needed)					
#	Name (First, Last)	Dispensing Practitioner License Number				
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

List	List all Dispensing Technicians – (Make copies of this page if additional space is needed)					
#	Name (First, Last)	Dispensing Technician License Number				
1						
2						
3						
4						
5						
6						
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12						
13						
14						
15						

Drug Storage A	Drug Storage Area				
Citation	Question	Yes	No	NA	
	Is the area clean and maintained in an orderly manner?				
NRS 639.1373	Current license(s) displayed?				
	Temperature compatible with drug storage requirements? (59-86 F)				
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)				
	Dedicated medication refrigerator?				
	Is refrigerator clean?				
	Is the temperature proper for the storage of drugs? (36 – 46 F)				
	Is the refrigerator sufficient size?				
	Is a daily temperature log maintained?				

Stock of Drugs	Stock of Drugs				
Citation	Question	Yes	No	NA	
NRS 585.410-	Are all pharmaceuticals in stock properly labeled?				
NRS 585.460	Name of Product?				
	Manufacturer's Name?				
	Lot Number?				
	Expiration Date?				
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?				
	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?				

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

Purchasing					
Citation	Question	Yes	No	NA	
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?				
	If purchasing compounded product is the product only administered to patients at your facility?				
List of wholesal	ers/manufacturers utilized by the dispensing practitioner:				

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.

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

Records	Records				
Citation	Question	Yes	No	NA	
	Prescriptions are ☐ Electronic ☐ Written				
NRS 454.223	Prescriptions contain the following:				
NAC 639.751	Name of patient and address if not immediately available to the practitioner?				
	Name/strength/quantity of drug prescribed?				
	Name of the practitioner and class of his/her license?				
	Practitioner's DEA number if the prescribed drug is a CS?				
	The initials of the dispensing practitioner involved in the preparation of the prescription dispensing?				
	The initials of the dispensing technician if involved in the preparation of the prescription dispensing?				
	The signature of the prescribing practitioner?				
	The directions for use?				
	How does the facility file completed prescriptions \Box Electronic \Box 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?				
NAC 639.742	Are all drugs ordered by the dispensing practitioner?				
(3)(a)	Are all drugs received and accounted for by the dispensing practitioner?				
NAC 639.745	Is a patient informed consent for the practitioner to dispense the medication documented for each product dispensed?				
NAC 639.918	Are prescriptions ever refilled using the same prescription number?				
	If yes, is a separate drug refill log maintained?				
	Does the practitioner maintain the dispensing records properly and retain them for 2 years?				
	Is a daily log kept that document which dispensing technician or trainee is assigned to each practitioner that day (ratio is 1:1)?				
	Have all dispensing technicians completed the 1 hour of Nevada Board of Pharmacy approved Law during their 2-year registration period?				

Citation	Question	Yes	No	NA
	Does the facility dispense controlled substances? (If "No" then skip to next section)			
	Does the facility dispense schedule II drugs?			
	If yes, are schedule II prescriptions filed separately from all other prescriptions?			
	Does the facility use the Controlled Substance Ordering System (CSOS) for ordering Schedule II controlled substances?			
	If yes, is the CSOS receiving document printed and attached to the invoice from the wholesaler?			
21 CFR 1305.06	Are schedule II order forms properly completed?			
NAC 453.410	Are schedule II invoices filed separately from all other invoices?			
NAC 639.485	Is a perpetual inventory completed for schedule II drugs?			
	Does the facility dispense schedule III-V controlled substances?			
NAC 453.410	Are schedule III-V invoices filed separately from all other records?			
21 CFR 1304.11	Has a biennial inventory of controlled substances been completed?			
	Date of most recent biennial inventory:			
	Does the facility report all controlled substances dispensed daily to the Nevada controlled substance task force (PMP)?			
	Does the facility report a zero dispensed report for each day when controlled substances are not dispensed?			
	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?			
	Has there been any theft or loss of controlled substances Since the last inspection?			
	If yes, was a DEA-106 form completed?			
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?			
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?			

Management					
Citation	Citation Question			NA	
	Does the practitioner understand he/she is legally responsible for the dispensing process?				
NRS 639.282	Are prescription drugs, previously dispensed to consumers, accepted for return?				
	Is the facility contracted with a vendor to supply computer software or pharmaceutical products?				
	Computer software vendor:				
	Pharmaceutical vendor:				

Notes	
require action will be sent to the email you frames stated to ensure compliance with	t of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that u indicate below. All unsatisfactory conditions must be corrected within the time laws and regulations governing your business. Please attach a copy of any have taken to this inspection form for future review on inspection.
Date:	
Dispensing Practitioner Printed Name:	
Dispensing Practitioner Signature:	
Email address for correspondence:	

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.

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 <u>NAC 639.7423</u>, 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 <u>NAC 639.7423</u>, 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 <u>NRS 639.23277</u> and <u>NAC 639.395</u>, <u>639.648</u> and <u>639.7423</u>, 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 <u>NAC 639.648</u> and <u>639.7423</u>, 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.

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 <u>NAC 639.7423</u>, 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 <u>NAC 639.7423</u>, 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 \underline{NRS} $\underline{639.2353}$ and \underline{NAC} $\underline{453.440}$;
- (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 \underline{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.

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 <u>NRS 453.126</u>, 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.
- Ê 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.