



FROM: Nevada State Board of Pharmacy Inspector

SUBJECT: Self-Assessment Inspection Process

The Board of Pharmacy's established self-assessment inspection process provides management 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 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.***

The procedure involves the following:

Print and fill out the self-assessment inspection form found on the website under your designated license type.. Retain the form and have it **readily available** in a packet so **if you are not present** when an inspector arrives, your staff can have it available.

Important: If your dispensing practitioner(s) are not on site all hours that your facility is open, please keep all dispensing records, invoices and documents in a secure location separate from the medications that are being dispensed. The key to this secure area can be kept in a secure area for access to records by the inspector when the practitioner is not on site.

1. An inspector will conduct a review of your operation. Observations, along with your findings, will assure understanding and compliance with Nevada law.
2. Effective 3/28/2014 LCB file R087-13 requires that each dispensing technician/dispensing technician trainee complete 1 hour of in-service training during the 2 year license renewal period. The in-service training must be a Nevada Board of Pharmacy approved jurisprudence program. The certificate of completion must be kept on file for a minimum of 2 years.
3. Attach a list of all controlled substances and dangerous drugs being dispensed. You are required to keep a perpetual inventory of all schedule II drugs. Have available for review your biennial controlled substance inventory. The inspector may review these documents during the inspection.

The following wording is repeated at the end of this inspection form and will become part of the record of the practitioner's acknowledgement that the practitioner understands and will comply with all statutes and regulations applicable to practitioner's dispensing license.

Each practitioner is required to personally order all medications that they will dispense. The practitioner must personally check in the medications ordered for dispensing. On arrival the practitioner must secure all medications that the practitioner will dispense so that no other person, including other practitioners, have access to the medications the practitioner will dispense under his/her dispensing practitioner registration except as allowed under NAC. All invoices for medications must be invoiced to the practitioner. (NAC 639.745) The practitioner also understands that he/she can only dispense medications that the practitioner prescribes, not medications prescribed by another practitioner. Each licensed Dispensing Practitioner by signing this document acknowledges his/her responsibility to comply with this and all other statutes and regulations related to dispensing.



DRUG STORAGE AREA: *(The inspection notice cover letter must be attached to this completed form).* Circle yes for compliant and no for non-compliant/or indicate NA by the question if the question is not applicable to your practice. You may make comments as needed.

Is the area clean & maintained in an orderly manner?	Yes	No
Current license(s) to prescribe/dispense drugs displayed? NRS 639.1373, 639.2351, 639.23505 NAC 649.742 (i)	Yes	No
Temperature compatible w/drug storage requirements (59-86° f)?	Yes	No
Does the facility carry products required to be stored in a refrigerator prior to dispensing or administering? (if NO skip to next question) NRS 639.282, NAC 639.525-527	Yes	No
Refrigerator?	Yes	No
Is it clean?	Yes	No
Is the temperature proper for the storage of drugs? (36-46 °F)	Yes	No
Sufficient size?	Yes	No
Daily temperature log maintained?	Yes	No

STOCK OF DRUGS:

Are all pharmaceuticals in stock properly labeled? NRS 585.410 - 585.460	Yes	No
Name of product?	Yes	No
Manufacture's name?	Yes	No
Lot Number?	Yes	No
Expiration date?	Yes	No

A list of all controlled substances and dangerous drugs being dispensed is printed and available to provide to the inspector. Yes No

Are all sterile multi-dose vials dated and discarded after 28 days? NAC 639.67057 Yes No

Are all single use/preservative free (PF) sterile vials, ampoules, etc. used for one patient and immediately discarded after being used? NAC 639.67057 Yes No

Are outdated, mislabeled, or adulterated drugs removed from stock and secured in an area where they will not be used to fill prescriptions? NRS 639.282, NAC 639.510 Yes No

Is there a procedure for monitoring the stock of drugs for outdated, mislabeled, or adulterated drugs? NRS 639.282, NAC 639.510 Yes No

Indicate the location of all segregated products _____

Are samples and immediate use drugs all in date and labeled properly? NRS 639.282, NAC 639.510 Yes No



CONTAINERS AND LABELING:

Are child resistant, moisture-proof containers used? NAC 639.740, 639.892		Yes	No
Is each container properly labeled? NRS 639.2801		Yes	No
The date filled?		Yes	No
The name of the dispensing practitioner?		Yes	No
Name of the patient?		Yes	No
Specific directions for use?		Yes	No
Expiration date of drug?		Yes	No
Name, strength & quantity of drug dispensed?		Yes	No
Alcohol/non prescribed drug warning?		Yes	No
Prescription number of prescription?		Yes	No
Is label affixed to immediate container?		Yes	No
Proper warning labels? NRS 585.450, NAC 453.470		Yes	No
Does the facility dispense products requiring reconstitution?		Yes	No
Adequate graduates for measuring?		Yes	No

RECORDS NRS 453.246, 454.286, 639.236, NAC 639.280(3), 639.879(2), 21 CFR 1304.04 (a), (g), (h):

(If the practitioner is not on site during facility hours, the records may be in a separate secure location so they are available for review on inspection)

Prescriptions are: **(circle)** (handwritten) (electronic)

Do the prescriptions contain? NRS 454.223			
Name of patient & address if not immediately available to the practitioner?		Yes	No
Name/strength/quantity of drug prescribed?		Yes	No
Name of the practitioner & class of his/her license?		Yes	No
Practitioner's DEA number if the prescribed drug is a controlled substance?		Yes	No
The initials of the dispensing practitioner and technician if involved in the preparation of the prescription dispensing? NAC 639.751		Yes	No
The directions for use?		Yes	No
The date the prescription was issued?		Yes	No
The signature of the prescribing practitioner?		Yes	No

How does the facility file completed prescriptions? **(circle)** (paper file) (computer file)

Is prescription data stored in the computer? NAC 639.745		Yes	No
Does the facility print and maintain a daily transaction log?		Yes	No
(if Yes) Does the printout contain all the required information?		Yes	No

Does the practitioner and dispensing technician or trainee initial and date the prescription(s) and initial the prescription label after filling? NAC 639.280(3),(e), 649.743, 639.879(2)

Yes No

Is a patient informed consent for the practitioner to dispense the medication(s) documented for each product dispensed?

Yes No

Are prescriptions ever refilled? **(using the same prescription number)**

Yes No



(if YES) is a separate drug refill log maintained? NAC 639.918 Yes No

Are prescriptions dispensed with Safety Caps only? Yes No

(if NO) is a non-safety cap log maintained? NAC 639.740 Yes No

Does the practitioner maintain the dispensing records properly & retain them for 2 years? Yes No

Does the facility maintain these records on site? 21 CFR 1304.04 (a) Yes No

CONTROLLED SUBSTANCES:

Does the facility dispense controlled substances? **(if NO skip to security section)** Yes No

Does the facility dispense schedule 2 substances? **(if YES)** Yes No

Are schedule II prescriptions filed separately from all other prescriptions? Yes No

Does the facility use the Controlled Substance Ordering System (CSOS) for ordering Schedule 2 controlled substances? Yes No

Are schedule 2 order forms properly completed? 21 CFR 1305.06 Yes No

Are schedule 2 records of receipt (invoices) filed separate from all other invoices? NAC 453.410 Yes No

Is the perpetual inventory accurate and complete? NAC 639.485 Yes No

Does the facility dispense schedule 3-5 controlled substances? Yes No

Are schedule III-V records of receipt (invoices) filed separately from all other records? NAC 453.410 Yes No

How are schedule III-V prescriptions filed? NAC 453.480/21 CFR 1304.04 (h)]
(single file) (separate file) (circle method of filing)

If in single file: are controlled prescriptions marked in a way to be readily retrievable? Yes No

Has a biennial inventory of controlled substances been completed? 21 CFR 1304.11, NRS 453.246

Biennial Inventory date: _____ Yes No

Does facility report all controlled substances dispensed daily to Nevada controlled substance task force? Yes No

Does the facility report a 0 dispensed report for each day where controlled substances are not dispensed? Yes No

You are required to submit electronically, daily, data on all controlled substances dispensed to the Prescription Controlled Substance Abuse Prevention Taskforce (PMP) Email: pmp@pharmacy.nv.gov

Phone: 775-687-5694 For Technical Assistance Call: 1-855-568-4767

Has the practitioner registered to access and is the practitioner accessing the PMP as required under SB459? **Required if a practitioner prescribes and/or dispenses any Schedule II, III, and IV medication.** Yes No

SECURITY NAC 453.400, NAC 639.285, NAC 639.898, NAC 639.520:

Are controlled substances/dangerous drugs kept in a deadbolt locked storage area? (Pictures from several angles of the medications in the locked storage area should be taken and include a clear view of expiration dates of medications. These will be reviewed and attached to the inspection form and will help facilitate the inspection if the practitioner is not on site). Yes No

Are licensed practitioner(s) the only person(s) with possession of a key? Yes No
 (A dispensing technician may only have the key when the practitioner is on site. Technicians in training cannot have a key to the medications at any time. A technician must have a registration for each practitioner they dispense for. NAC 639.743

A daily log is kept that documents which dispensing technician or trainee is assigned to each practitioner that day (Ratio of 1:1 practitioner to dispensing technician) Yes No

Have all dispensing technicians completed 1 hour of Nevada Board of Pharmacy approved Nevada law? (Attach certificates) <http://bop.nv.gov/Services/CE/> Yes No



Does the facility have an alarm system? (recommended)

Provider: _____

Yes No

If dispensing controlled substances:

Has there been any theft or loss of controlled substances since the last inspection?

Yes No

Was a DEA 106 loss of theft or loss of controlled substances completed?

Yes No

(if YES): Was the theft or loss of all controlled substances properly reported to Nevada State Board of Pharmacy, DEA? NRS 453.568 (Must be reported within 10 days of the loss.)

Yes No

Was a DEA form 41, voluntary surrender of controlled substances, completed for any controlled substances destroyed by the practitioner? 21 CFR 1307.21, NAC 639.050

Yes No

Is access to the controlled substance task force data base limited to the practitioner and, if applicable, their designated agent?

Yes No

How is the access protected?

Does each exam room have signage notifying the patient may request that the symptom or purpose for which a drug is prescribed be included on the label of prescriptions you prescribe? NRS 639.2352

Yes No

How are prescription pads secured? _____

Who has access to prescription pads? _____

MANAGEMENT:

Do you have an internet website?

Yes No

If yes, what is the web address? _____

Does the Practitioner(s) understand he/she is legally responsible for the dispensing operation?

Yes No

Are prescription drugs, previously dispensed to consumers, accepted for return?

NRS 639.282

Yes No

Is the facility contracted with a vendor to supply computer software or pharmaceutical products? (if yes enter contact information)

Yes No

Computer software vendor's Name/Address/Phone #	Pharmaceutical Products vendor's Name/Address/Phone #

Are you purchasing for sale or dispensing to your patients, from sources other than a Nevada licensed manufacturer of the pharmaceutical product or a Nevada licensed wholesaler, any compounded pharmaceutical product that is available commercially? NAC 639.757

Yes No

- If you do, provide a complete list of products (Invoices). List the provider(s) of the compounding pharmaceutical product with the provider's complete contact information.

Are you purchasing for administration to your patients, from sources other than a Nevada licensed manufacturer of the pharmaceutical product or a Nevada licensed wholesaler, any compounded pharmaceutical product that is available commercially? NAC 639.757

Yes No

- If you do, provide a complete list of products (Invoices). List the provider(s) of the compounding pharmaceutical product with the provider's complete contact information.



If you are purchasing commercially available (manufactured and FDA approved) products to dispense or administer;

- Verify that the product’s provider is licensed to sell to you by checking the Board of Pharmacy website.
- If you are purchasing compounded products and are not sure if the product is available commercially, contact the provider of the product to verify if the product is available commercially.
- A pharmacy cannot compound a pharmaceutical product for sale to a practitioner for the purpose of resale by the practitioner.
- A pharmacy cannot compound a pharmaceutical product that is available commercially unless there is a significant medical reason for the alteration in the commercial prescription product. Altering includes, but is not limited to, changing one or more inactive ingredients or strength of the active ingredient. The documentation of the reason for altering the commercial product should be noted in the patient’s chart and on the written prescription dispensed by the pharmacy.

AB 537 amended the following Sections 1. NRS 630.306 Sec. 2. NRS 631.3475 Sec. 3. NRS 632.320 Sec. 4. NRS 633.511 Sec. 5. NRS 635.130 Sec. 6. NRS 636.295

- It is a violation of NRS for a practitioner to :
 - Knowingly procuring or administering a controlled substance or a dangerous drug as defined in chapter 454 of NRS that is not approved by the United States Food and Drug Administration, unless the unapproved controlled substance or dangerous drug:
 - (a) Was procured through a retail pharmacy licensed pursuant to chapter 639 of NRS;
 - (b) Was procured through a Canadian pharmacy which is licensed pursuant to chapter 639 of NRS and which has been recommended by the State Board of Pharmacy pursuant to subsection 4 of NRS 639.2328; or(c) Is marijuana being used for medical purposes in accordance with chapter 453A of NRS.

Currently there are no Canadian pharmacies licensed by the Nevada State Board of Pharmacy.

Remarks:



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

Inspector: _____ Dated: _____

Practitioner/or authorized agent: _____ Dated: _____

If signed above by an authorized agent, this inspection approval is not valid until the practitioner signs, dates and faxes this page to the inspector.

I understand that I am responsible for compliance with all dispensing practitioner NAC's and NRS's and that each practitioner in the facility that dispenses must have a dispensing practitioner license. (each dispensing practitioner must sign, print name and date)

Practitioner: _____ Dated _____

Practitioner: _____ Dated _____

Practitioner: _____ Dated _____

Practitioner: _____ Dated _____

Practitioner: _____ Dated _____

It is the responsibility of each practitioner to review this inspection form and contact the inspector with any questions the practitioner may have any on deficiencies or notations made by the inspector. It is each practitioner's responsibility to make sure all deficiencies are corrected.