## **NEVADA STATE BOARD OF PHARMACY**

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

## <u>Automated Drug Dispensing System Inspection: Instruction Sheet and Form</u> (Revised 05/2023)

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 this 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.

If this is the first time the Automated Drug Dispensing System (System) is being inspected, and this is your "Pre-Inspection", please have this form completed and available for review on the day you are scheduled for your "Pre-Inspection".

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

- 1. Written policies that sets forth:
  - a. The duties of all persons who are authorized to access the system; and
  - b. The procedures for:
    - i. Maintaining the security of the prescription drugs stored in the system during the maintenance and repair of the system;
    - ii. The preparation of an inventory of the prescription drugs stored in the system; and
    - iii. Stocking the system with prescription drugs.

	Pharmacy Information					
Date Completed:						
Pharmacy Name:						
Pharmacy License #:						
Pharmacy Address:						
Pharmacy City, State, Zip:						
Pharmacy Telephone #:						
Pharmacy Fax #:						
Pharmacy Email:						
Managing Pharmacist Name:						
Managing Pharmacist start date:						
NVBOP Inspector:						
	Automa	ated Drug Dispensing S	System (System) Information			
Name of System:						
Make:						
Model/MFG #:						
Serial #:						
MFG Name:						
Name of location for the System:						
Location Address:						
Location City, State, Zip:						
200000000000000000000000000000000000000						
List all registered pharmacists who	will be approving th	ne prescription drugs to l	ne used in the system.			
(Make copies of this page if additi			se used in the system.			
# Name (First, Last)		License Number	Position			
1			1000000			
2						
3						
4						
5						
6						
7						
8						
9						
10						
	s pharmacoutical	tachnician's ar intern	pharmacist's employed by the pharmacy			
that will have access to the system			pharmacist's employed by the pharmacy			
(Make copies of this page if additi						
# Name (First, Last)	ional space is need	License Number	Position			
1						
2						
3						
4						
5						
6						
7						
7						
9						

Automated D	Automated Drug Dispensing System					
Citation	Question	Yes	No	NA		
NAC 639.718	The system ONLY contains prescription drugs:					
	i. Approved for use in the system by a registered pharmacist employed by the					
	pharmacy; and					
	ii. For which the prescription has been processed, verified, and completed in the same					
	manner as a prescription for drugs that are delivered manually by the pharmacy, including the provision of printed medication guides and any other information					
	required pursuant to NAC 639.707.					
	The system DOES NOT contain:					
	i. Controlled substances included in schedule II; or					
	ii. Controlled substances included in schedules III, IV, and V unless authorized by the					
	Drug Enforcement Administration of the United States Department of Justice to					
	dispense such substances.					
	The system control and track access to the system for stocking, cleaning, maintenance, or any					
	other purpose to ensure that access to the system can be obtained only by a registered					
	pharmacist, pharmaceutical technician, or intern pharmacist employed by the pharmacy					
	using user-based access technology.					
	The system is secure from unauthorized access to and removal of prescription drugs.					
	The system is owned or leased by the pharmacy that holds the license for the system and					
	operated under the supervision and control of that pharmacy.					
	The system monitors the temperature of the system or is able to have a device installed to					
	monitor the temperature of the system. Such monitoring includes, without limitation, an					
	alarm that records when the temperature of the system reaches a level outside the range					
	compatible with the proper storage of a prescription drug and a method to notify the					
	pharmacy of the temperature change.					
	The system creates and maintains a complete, accurate and readily retrievable record of all					
	transactions. The record includes, without limitation:					
	1. The name, strength, quantity, and form of dosage of each prescription drug stocked,					
	inventoried, removed, or dispensed from the system;					
	2. Each day and time the system is accessed;					
	3. An inventory of the prescription drugs stored in the system; and					
	4. The identity of each person who accesses the system.					
	The system authorizes access only to patients who previously have indicated to the pharmacy					
	their desire to have their prescription drugs dispensed by the system.					
	The system provides a method to identify the patient and dispense a prescription drug only					
	to the patient or to an authorized agent of the patient.  The system dispenses one, any combination or all of the prescription drugs available to a					
	patient at the option of the patient at the time that the patient removes the prescription					
	drugs from the system.					
	The system records the date and time that the patient removes the prescription drugs from					
	the system.					
	The system informs a patient:					
	1. If the patient is using the system at the time that the pharmacy is open, that the					
	patient may discuss questions and concerns regarding the prescription drug with a					
	pharmacist at the pharmacy or through the user-based access technology.					
	2. If the patient is using the system at the time that the pharmacy is closed, that the					
	patient may discuss questions and concerns regarding the prescription drug through					
	the user-based access technology.					
	3. That the patient may choose not to purchase the prescription drug from the system					
	at any time before the system dispenses the prescription drug.					
	"User-based access technology" means software or hardware that restricts access to an					
	automated drug dispensing system to authorized users by requiring two-factor					
	authentication. Authentication factors may include, without limitation, knowledge, hardware					
	tokens or biometric information. The technology includes, without limitation, an audio-visual					
	function that allows the patient to communicate, in real time, with a registered pharmacist					

	who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and NAC 639.708.			
NAC 639.718	The system dispenses all prescription drugs in containers labeled in conformance with NRS 639.2801.			
	The system is installed in such a place and manner that a person is unable to remove the system from its location and any attempts to obtain access to the system without authorization are visible to the pharmacist of the pharmacy, either through the system being in view of the pharmacist or by real-time audio-visual communication technology or audio-visual recording technology.  The system is equipped with user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate, in real time, with a			
	registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and NAC 639.708.			
	The pharmacy that dispenses prescription drugs by the system maintains a written policy that sets forth:  a. The duties of all persons who are authorized to access the system; and			
	<ul> <li>b. The procedures for:</li> <li>i. Maintaining the security of the prescription drugs stored in the system during the maintenance and repair of the system;</li> <li>ii. The preparation of an inventory of the prescription drugs stored in the</li> </ul>			
	system; and iii. Stocking the system with prescription drugs.			
	The pharmacy that dispenses prescription drugs through the system complies with all applicable federal and state recordkeeping requirements and maintains those records in a readily retrievable manner separate from other pharmacy records.			
	Prescription drugs stored in the system are deemed part of the inventory and the responsibility of the pharmacy that holds the license for the system. Prescription drugs dispensed from the system are deemed to have been dispensed by that pharmacy.			
	The license for the system is posted on the system so that the license is visible to the public.			

## General guidelines related to receipt of prescriptions:

Transmission of prescriptions be facsimile machine – Written prescriptions and faxed prescriptions, regardless of method of receipt via standalone fax, by a computerized fax queue or other fax method, require the handwritten signature of the prescribing practitioner. A prescription received via fax or written is not a legal prescription without a handwritten signature. A pharmacist must validate that a prescription received by fax in a computer fax queue has a handwritten signature and not an electronically signed or stamped signature.

A practitioner may sign a paper prescription in the same manner as he or she would sign a check or legal document. Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.

Electronic transmission of prescription – The electronic signature must be digitally signed with at least all the information required under part 1306, Prescriptions, of 21 CFR. A prescription that is digitally signed with a practitioner's private key may be transmitted to a pharmacy without the digital signature.

Notes	
	agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that
	ail you indicate below. All unsatisfactory conditions must be corrected within the iance with laws and regulations governing your business. Please attach a copy of
	ection you have taken to this inspection form for future review on inspection.
Date:	
Pharmacist Printed Name:	
Pharmacist Signature:	
Email address for correspondence:	