NEVADA STATE BOARD OF PHARMACY

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

Automated Drug Dispensing System for Reproductive Healthcare Centers Inspection: Instruction Sheet and Form

(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 set 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.

Reproductive Healthcare Center Information	
Date Completed:	
Facility Name:	
Facility Address:	
Facility City, State, Zip:	
Facility Fax #:	
Facility Telephone:	
Facility Email:	
Medical Director Name:	
NVBOP Inspector:	

Automated Drug Dispensing System (System) Information	
Name of System:	
Make:	
Model/MFG #:	
Serial #:	
MFG Name:	

List all registered dispensing practitioners that will be dispensing from the automated drug dispensing system in which a shared inventory is maintained. (Make copies of this page if additional space is needed)		
#	Name (First, Last)	Dispensing Practitioner Registration #
1		
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Automated Drug Dispensing System				
Citation	**Question**	**Yes**	**No**	**NA**
R180-22	The system only contains dangerous drugs, excluding compound drug products, for treatment in reproductive health care: i. Approved for use in the system by a dispensing practitioner; 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 a dispensing practitioner pursuant to NAC 639.742 and 639.745, except that the requirements of paragraph (e) of subsection 3 of NAC 639.742 do not apply.			
	The system controls and tracks 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 dispensing practitioner practicing at the reproductive healthcare center.			
	The system is secure from unauthorized access to and removal of prescription drugs.			
	The system is owned or leased by the reproductive healthcare center that obtained the license for the system and operated under the supervision and control of that reproductive healthcare center.			
	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 reproductive healthcare center of the temperature change.			
	The system creates and maintains a complete, accurate and readily retrievable record of all transactions. The record includes, without limitation: i. The name, strength, quantity, and form of dosage of each prescription drug stocked, inventoried, removed or dispensed from the system; ii. Each day and time the system is accessed; iii. An inventory of the prescription drugs stored in the system; and iv. The identity of each person who accesses the system.			
	The system authorizes access only to patients who previously have indicated to the dispensing practitioner who prescribed the drug 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: i. If the patient is using the system at the time that the reproductive healthcare center is open, that the patient may discuss questions and concerns regarding the prescription drug with the dispensing practitioner in person, if available, or through the user-based access technology. ii. If the patient is using the system at the time that the reproductive healthcare center is closed, that the patient may discuss questions and concerns regarding the prescription drug through the user-based access technology. iii. 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 dispensing practitioner who has access to any patient record necessary for counseling the patient in compliance with			

	NAC 639.707 and NAC 639.708.			
	The system dispenses all prescription drugs in containers labeled in conformance with NRS 639.2801.			
R180-22	The system is installed in such a place and manner that a person is unable to remove the system from its location or obtain access to the system without authorization. The system is monitored by real-time audio-visual 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 dispensing practitioner who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and NAC 639.708.			
	The reproductive healthcare center 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 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.			
	The dispensing practitioner(s) practicing at the reproductive healthcare center 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 medical records.			
	Prescription drugs stored in the system is deemed part of the inventory and the responsibility of each dispensing practitioner that uses the system at the reproductive healthcare center that holds a license for the system. Prescription drugs dispensed from the system is deemed to have been dispensed by that dispensing practitioner or those dispensing practitioners, as applicable.			
	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

Your location will be inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action will be sent to the email you indicate below. **All unsatisfactory conditions must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business. Please attach a copy of any documentation and corrective action you have taken to this inspection form for future review on inspection.**

Date:	
Medical Director Printed Name:	
Medical Director Signature:	
Email address for correspondence:	