

**PROPOSED REGULATION OF THE
STATE BOARD OF PHARMACY**

LCB File No. R002-15

July 30, 2015

EXPLANATION – Matter in *italics* is new; matter in brackets ~~[omitted material]~~ is material to be omitted.

AUTHORITY: §§1 and 2, NRS 639.070.

A REGULATION relating to the practice of pharmacy; requiring certain entities collecting controlled substances to provide certain notification and a copy of a certain federally required form to the State Board of Pharmacy; clarifying standards for the disposal of controlled substances; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Under existing law, the State Board of Pharmacy may adopt regulations governing the storage, handling and security of drugs and medicines. (NRS 639.070)

Federal law authorizes pharmacies, hospitals and other entities authorized to handle controlled substances to register with the Drug Enforcement Administration for authority to collect controlled substances. Such entities may conduct “mail-back” programs for the return of controlled substances and may maintain collection receptacles for the return of controlled substances. (21 C.F.R. §§ 1317.40, 1317.70, 1317.75) **Section 1** of this regulation requires an entity conducting a mail-back program or maintaining a collection receptacle to notify the Board that it has registered with the Drug Enforcement Administration. **Section 1** also requires such an entity to submit to the Board a copy of a certain form required to be submitted to the Drug Enforcement Administration.

Existing federal law provides standards for the disposal of controlled substances by entities authorized to handle and dispose of controlled substances. (21 C.F.R. parts 1300, 1301, 1304, 1305, 1307, 1317) Existing regulation also provides standards for the disposal of controlled substances. (NAC 639.498) **Section 2** of this regulation deletes the provisions of state regulatory law providing standards for the disposal of controlled substances and clarifies that the disposal of controlled substances must be done pursuant to federal law.

Section 1. NAC 639.050 is hereby amended to read as follows:

639.050 1. Upon the discontinuance of a controlled substance, a controlled substance becoming outdated or the demise of a patient at a facility for skilled nursing or facility for

intermediate care which is licensed by the Division of Public and Behavioral Health of the Department of Health and Human Services, any remaining controlled substance dispensed to the patient must be placed in a secured locked compartment. The controlled substance must be secured in the locked container until destroyed in the manner prescribed in NAC 639.498.

2. Each practitioner or pharmacy shall physically separate each controlled substance which is outdated, damaged, deteriorated, misbranded or adulterated from the balance of its stock medications. The practitioner or pharmacy shall destroy such controlled substances at least once each year. The practitioner or pharmacy shall complete Form DEA-41 of the Drug Enforcement Administration, "Registrants Inventory of Drugs Surrendered," to acknowledge the destruction of the controlled substances.

3. *Any entity that is authorized pursuant to federal law to collect controlled substances and conducts a mail-back program to collect controlled substances or maintains collection receptacles for controlled substances shall provide to the Board:*

(a) Written notification that the entity has registered with the Drug Enforcement Administration to obtain authorization to be a collector; and

(b) A copy of each Form DEA-41 submitted to the Drug Enforcement Administration.

4. This section does not apply to controlled substances packaged in manufacturer's unit-dose packages which are governed by the provisions of NRS 639.267.

Sec. 2. NAC 639.498 is hereby amended to read as follows:

639.498 1. Except as otherwise provided in subsection 2:

(a) At least once each month, the director or a licensed consulting pharmacist shall destroy, on the premises of the facility, the controlled substances described in subsection 1 of NAC 639.050.

(b) If the director destroys the controlled substances, the licensed consulting pharmacist shall witness the destruction of the controlled substances. If the licensed consulting pharmacist destroys the controlled substances, the director shall witness the destruction of the controlled substances.

2. The director may designate a nurse licensed pursuant to chapter 632 of NRS to carry out his or her duties pursuant to this section. The licensed consulting pharmacist may designate a pharmacist licensed pursuant to chapter 639 of NRS to carry out his or her duties pursuant to this section.

3. The controlled substances must be destroyed ~~by:~~

- ~~—(a) Flushing them down the toilet or hopper;~~
- ~~—(b) If a container for waste disposal is used, placing the controlled substances in the water in the container for disposal; or~~
- ~~—(c) If the controlled substance is stored in a vial, ampule or other glass container, breaking the container and placing its contents into a container for waste disposal.~~

in accordance with 21 C.F.R. Parts 1300, 1301, 1304, 1305, 1307 and 1317 and any other provision of federal law governing the destruction or disposal of controlled substances.