LCB File No. R034-02

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Section 1. NAC 639.745 shall be amended as follows:

1. Each practitioner who is registered with the board to dispense controlled substances and dangerous drugs and dispenses such products for use by his patients outside his presence, shall:

(a) Keep complete, accurate and readily retrievable records of each drug purchased and dispensed. ***A record for each drug dispensed to a patient must include:*** ~~[Each written prescription must be serially numbered and kept in numerical order in a single file for all dispensing practitioners, including the physician's assistants and prescribing nurses practicing at the same location.~~

~~(b) Ensure that each prescription entry contains:]~~

(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 name of the prescribing practitioner and classification of his license.~~

~~(4) The practitioner's registration number issued by the Drug Enforcement Administration of the United States Department of Justice, if the product is a controlled substance.~~

~~(5) The initials of the dispensing practitioner, if the dispensing practitioner did not prescribe the controlled substance or dangerous drug.]~~

~~[(6)]~~ ***(3)*** The directions for use.

~~[(7)]~~***(4)*** The date the prescription was issued.

~~[(8) The signature of the prescribing practitioner.]~~

(5) A unique identifying number.

~~[(c)]~~ ***(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.

~~[(d)]~~ ***(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.

~~[(e)]~~ ***(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.

~~[(f)]~~ ***(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) Count the drug from a stock bottle if a stock bottle is used, place the drug in the dispensing container, place the label on the dispensing container, and give the dispensing container to the patient. The dispensing practitioner may not delegate any of the functions in this subsection to any other employee or person.

2. 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. The record regarding the dispensing of a drug to a patient made and kept pursuant to section 1(a) may be maintained on paper or in a computer.

(a) If the record is maintained on paper, the record shall:

(1) Be in the form of a prescription in conformance with NRS 639.2353 and NAC 453.440;

(2) Contain on the front of the prescription a certification initialed and dated by the patient that the patient had been advised by the practitioner of the patient's ability to obtain a written prescription under paragraph 2 and that the patient agreed to have the practitioner dispense the drug; and

(3) Be serially numbered and kept in numerical order in a single file for all dispensing practitioners, including the physician's assistants and prescribing nurses practicing at the same location.

(b) If the record is maintained in a computer, the record shall:

(1) Be capable of being searched by any of the data elements required in subsection 1(a);

(2) Be accompanied by a written certification initialed and dated by the patient that the patient had been advised by the practitioner of the patient's ability to obtain a written prescription under paragraph 2 and that the patient agreed to have the practitioner dispense the drug, which certification must be maintained in the patient's file;

(3) Be capable of producing a written prescription in conformance with NRS 639.2353 and NAC 453.440 upon request from the patient.

Section 2. NAC chapter 639 shall be amended to add the following new language:

1. A practitioner who intends to dispense dangerous drugs or controlled substances must apply to the board on an application provided by the board. A practitioner must make separate application for each practice site from which he intends to dispense dangerous drugs or controlled substances.

2. The board shall not issue a registration to dispense dangerous drugs or controlled substances to a practitioner whose site of practice is within five miles of a pharmacy unless:

(a) The site of practice of the practitioner is owned or operated by a corporation that is exempt from federal taxation pursuant to section 501(c)(3) of the Internal Revenue Act; or

(b) The practitioner can demonstrate a compelling need by patients for the particular dispensing services intended to be offered by the practitioner.

3. In considering whether a practitioner has demonstrated a compelling need by patients for the particular dispensing services the practitioner intends to offer, the board may consider factors, including, without limitation:

(a) The location of the practice site;

(b) The specialty or type of practice the practitioner intends to offer;

(c) The drugs the practitioner intends to offer;

(d) The ownership of the practice or the practice site and the source of funds that will be used to pay the practitioner;

(e) The history of the practitioner or the practice's owner, including, but not limited to:

(1) Administrative or other legal actions by the board or any other state, federal, or local governmental agency;

(2) Criminal background;

(3) Involvement in internet or illicit sales of drugs; and

(4) Other similar matters involving the background or activities of the practitioner or the practice's owner;

(f) The need in the community that would foreseeably be served by the practitioner for the specialty or type of practice the practitioner intends to offer and whether existing pharmacies and practice sites can and are already fulfilling that need;

(g) Any other factors the board deems helpful in its determination regarding whether the proposed dispensing practice is bona fide and whether quality patient care would be promoted by the dispensing practice.

Section 3. Practitioners who are registered or who have applied for registration prior to the effective date of this regulation shall have until October 31, 2002 to bring their practices into conformance with this regulation.

Workshop 3/7/02