REVISED PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R039-21

February 7, 2022

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

AUTHORITY: §§ 1-6, NRS 639.070 and section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085); § 7, NRS 639.070 and 639.210.

A REGULATION relating to pharmacy; prescribing the training that is required for a pharmacist to be authorized to prescribe, dispense and administer certain drugs for preventing the acquisition of human immunodeficiency virus; prescribing certain requirements concerning the prescribing, dispensing and administering of such drugs by a pharmacist; adopting certain publications by reference; providing that failure by a pharmacist to make certain reports is unprofessional conduct; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the State Board of Pharmacy to adopt regulations that establish a protocol to authorize a pharmacist to: (1) order and perform laboratory tests that are necessary for therapy that uses a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus; and (2) prescribe, dispense and administer any of those drugs to a patient. (Section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085)) Existing law defines "drug" to include devices intended for use in the prevention of disease. (NRS 639.007)

Section 2 of this regulation provides that a latex or polyurethane prophylactic device is a drug and, therefore, that a pharmacist may prescribe such devices where approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus. **Section 3** of this regulation requires a pharmacist to complete certain courses of training concerning the prescribing, dispensing and administering of drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus before prescribing, dispensing or administering such drugs. **Section 3** also requires a pharmacist who prescribes, dispenses or administers such drugs to maintain and make readily available proof of completion of each course of training. **Section 3** additionally requires such a pharmacist to maintain professional liability insurance coverage of at least $1,000,000.

Section 4 of this regulation requires a pharmacist to complete an assessment of the patient before prescribing, dispensing or administering a preexposure prophylaxis drug. **Section 4** authorizes a pharmacist to prescribe, dispense or administer a postexposure prophylaxis drug immediately upon the request of a patient who has been exposed to the human

immunodeficiency virus and requires the pharmacist to complete an assessment to continue the treatment after the initial prescribing, dispensing or administering of such a drug. **Section 4** also requires a pharmacist who prescribes, dispenses or administers a preexposure prophylaxis drug or postexposure prophylaxis drug to provide counsel and certain information to the patient.

Section 5 of this regulation adopts by reference certain guidelines from the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. **Section 6** of this regulation requires a pharmacist to comply with those guidelines and all applicable federal and state laws when prescribing, dispensing and administering drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus. **Section 6** authorizes a pharmacist to prescribe, dispense and administer not more than a 30-day supply of such a drug without completing the laboratory testing required by those guidelines and **section 4** under certain circumstances. **Section 6** additionally requires a pharmacist who prescribes, dispenses or administers such a drug to establish and adhere to a plan of care for treatment using the drug.

Existing law: (1) requires providers of health care to make certain reports concerning cases of communicable diseases, drug overdoses and attempted suicides; and (2) deems a pharmacist to be a provider of health care for that purpose. (NRS 441A.110, as amended by section 5 of Senate Bill No. 229, chapter 290, Statutes of Nevada 2021, at page 1663, NRS 441A.150, as amended by section 6.4 of Assembly Bill No. 181, chapter 185, Statutes of Nevada 2021, at page 864) **Section 7** of this regulation provides that the failure by a pharmacist to comply with those reporting requirements is unprofessional conduct, thereby subjecting the pharmacist to disciplinary action. (NRS 639.210)

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 6, inclusive, of this regulation.

Sec. 2. ***For the purposes of section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), and sections 2 to 6, inclusive, of this regulation, "drug" includes a latex or polyurethane prophylactic device, including, without limitation, a latex or polyurethane condom.***

Sec. 3. ***1. A pharmacist may prescribe, dispense and administer drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), if the pharmacist has completed a course of training concerning the prescribing, dispensing and administering of such drugs. The course must be:***

(a) Approved by the Accreditation Council for Pharmacy Education, or its successor organization; or

(b) Offered by a college of pharmacy or department of pharmacy at a university accredited by the Accreditation Council for Pharmacy Education, or its successor organization.

2. A pharmacist who prescribes, dispenses or administers drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), shall maintain and make readily available proof of completion of a course completed pursuant to subsection 1 while the pharmacist prescribes, dispenses or administers such drugs, as applicable, and for at least 2 years following that prescribing, dispensing or administering.

3. A pharmacist who prescribes, dispenses or administers drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), shall maintain professional liability insurance coverage of at least $1,000,000.

Sec. 4. *1. Except as otherwise provided in subsection 2 of section 6 of this regulation, a pharmacist shall, before prescribing, dispensing or administering a preexposure prophylaxis drug pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), complete an assessment of the patient that includes, without limitation:*

(a) A test for human immunodeficiency virus;

(b) A test for renal function;

(c) A test for hepatitis B; and

(d) An evaluation for any signs and symptoms of acute human immunodeficiency virus infection.

2. A pharmacist may prescribe, dispense or administer a postexposure prophylaxis drug pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), immediately upon the request of a patient who has recently been exposed to human immunodeficiency virus. Except as otherwise provided in subsection 2 of section 6 of this regulation, the pharmacist shall, before continuation of treatment using such drugs beyond the initial prescribing, dispensing or administering, complete an assessment of the patient that includes, without limitation:

(a) A test for human immunodeficiency virus;

(b) A pregnancy test if the patient is a woman of child-bearing age;

(c) A test for liver function;

(d) A test for renal function;

(e) A test and screening for sexually transmitted infections;

(f) A test for hepatitis B; and

(g) A test for hepatitis C.

3. Upon prescribing, dispensing or administering a preexposure prophylaxis drug or a postexposure prophylaxis drug pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), a pharmacist shall counsel the patient and provide information on the drug dispensed or administered, including, without limitation:

(a) The proper administration and storage of the drug;

(b) The proper dosage of the drug;

(c) The effectiveness of the drug;

(d) The potential side effects of the drug;

(e) The need to be regularly tested for human immunodeficiency virus;

(f) The need to adhere to the treatment; and

(g) If applicable, the inability of the drug to prevent sexually transmitted infections other than the human immunodeficiency virus.

4. As used in this section:

(a) "Postexposure prophylaxis drug" means a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus that is designed to be administered after exposure to the virus.

(b) "Preexposure prophylaxis drug" means a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus that is designed to be administered before exposure to the virus.

Sec. 5. ***1. Except as otherwise provided in subsection 2, the following publications are hereby adopted by reference:***

(a) Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update - A Clinical Practice Guideline, published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. A copy of this publication may be obtained free of charge at the Internet address https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf, or, if that Internet website ceases to exist, from the Board.

(b) Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV - United States, 2016, published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. A copy of this publication may be obtained free of charge at the Internet address https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf, or, if that Internet website ceases to exist, from the Board.

2. Except as otherwise provided in this subsection, the most current version of a publication adopted by reference in subsection 1 which is published will be deemed to be adopted by reference. The Board will periodically review and determine, within 30 days after the review, whether any change made to a publication listed in subsection 1 is appropriate for application in this State. If the Board does not disapprove a change to an adopted publication within 30 days after the review, the change is deemed to be approved by the Board.

Sec. 6. *1. Except as otherwise provided in subsection 2, a pharmacist shall comply with the publications adopted by reference in section 5 of this regulation and all applicable federal and state laws and regulations, including, without limitation, laws and regulations relating to labeling of prescriptions and keeping records, when prescribing, dispensing and administering drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085).*

2. A pharmacist may prescribe, dispense and administer up to a 30-day supply of a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus to continue treatment without completing the requirements

for laboratory testing prescribed in section 4 of this regulation or the publications adopted by reference in section 5 of this regulation if the pharmacist:

(a) Makes a good faith effort to obtain and review the laboratory history of the patient;

(b) Completes an assessment of the patient;

(c) Reviews potential adverse side effects with the patient; and

(d) Determines that the benefit of continuing the treatment outweighs the risk of not continuing the treatment.

3. A pharmacist who prescribes, dispenses or administers a drug approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus pursuant to section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201 (NRS 639.28085), must establish and adhere to a plan of care for treatment using the drug. The plan must include, without limitation, support and ongoing assessment as required by the publications adopted by reference in section 5 of this regulation.

Sec. 7. NAC 639.945 is hereby amended to read as follows:

639.945 1. The following acts or practices by a holder of any license, certificate or registration issued by the Board or any employee of any business holding any such license, certificate or registration are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest:

(a) Manufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations.

(b) Except as otherwise provided in NRS 639.2583 to 639.2808, inclusive, for substitutions of generic drugs, dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed, unless the express permission of the orderer

or prescriber is obtained and, in the case of a written prescription, unless the following information is recorded on the prescription by the person obtaining permission:

(1) The date on which the permission was granted;

(2) The name of the practitioner granting the permission;

(3) The name of the person obtaining the permission;

(4) The name of the drug dispensed; and

(5) The name of the manufacturer or distributor of the drug.

(c) Using secret formulas.

(d) Except as otherwise provided by subsection 2 of NRS 639.2396, failing strictly to follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling, the content of the label of the prescription or giving a copy of the prescription or chart order to any person except as permitted by law.

(e) Failing to confer with the person writing, making or ordering a prescription or chart order if there is an error or omission in it which should be questioned.

(f) Operating a pharmacy at a location other than the location at which the pharmacy is licensed to operate.

(g) Supplying or diverting drugs, biologicals, medicines, substances or devices which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles.

(h) Performing or in any way being a party to any fraudulent or deceitful practice or transaction.

(i) Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

(j) Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada.

(k) Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration.

(l) Violating any term or condition of a subpoena or order issued by the Board or the staff of the Board.

(m) Failing to provide any document, data or information that is required to be made and maintained pursuant to chapters 453, 454, 585 and 639 of NRS and chapters 453, 454, 585 and 639 of NAC to a member of the Board or a member of the staff of the Board upon his or her request.

(n) Except as otherwise provided in subsection 2:

(1) Dispensing a drug as a dispensing practitioner to a patient or animal or owner of an animal with whom the dispensing practitioner does not have a bona fide therapeutic relationship; or

(2) Prescribing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship.

(o) Failure by a pharmacist to comply with the provisions of chapter 441A of NRS and chapter 441A of NAC concerning the reporting of cases of communicable diseases, drug overdoses and attempted suicides.

2. It is not unprofessional conduct or conduct contrary to the public interest for a practitioner to prescribe or dispense a drug under the circumstances described in paragraph (n) of

subsection 1 if the drug is prescribed or dispensed in accordance with either publication adopted by reference in section 1 of this regulation.

3. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ.

4. For the purposes of this section, a bona fide therapeutic relationship between the patient and practitioner shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics within or outside of this State or the United States by the practitioner within the 6 months immediately preceding the date the practitioner dispenses or prescribes a drug to the patient and, as a result of the examination, the practitioner diagnosed a condition for which a given drug therapy is prescribed.