Nevada State Board of Pharmacy

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February 1, 2022

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of
Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will conduct a Public Hearing on Thursday, March 3, 2022, at 9:00 a.m. Public access for the meeting is:

Pursuant to NRS 241.023(1)(c), the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapters 453 and/or 639 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

A. Amendment of Nevada Administrative Code (NAC 639.) The proposed amendments will create a new section to implement the provisions of Senate Bill 325 requiring the Board to adopt regulations that establish requirements to allow a pharmacist to dispense drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus. (LCB File R039-21)

1. The need for and the purpose of the proposed regulation or amendment.

The proposed regulations will authorize a pharmacist to prescribe, dispense, and administer certain drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus under a protocol. Implementing these regulations will expand access to pre-exposure and post-exposure human immunodeficiency preventative medications.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no adverse economic impact from these regulations on the regulated entities or on the public. The beneficial effects will expand access to pre-exposure and post-exposure human immunodeficiency preventative medications.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be expanded access to pre-exposure and post-exposure human immunodeficiency preventative medications.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation amendment.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation amendment overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

This regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation amendments of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments, in written form, to the Board at pharmacy@pharmacy.nv.gov or to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521. Written submissions must be received by the Board on or before January 13, 2022. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request.

Pursuant to NRS 233B.064(1), upon adoption of any regulation, the Board, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to Governor's Declaration of Emergency Directive 006.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R039-21

November 4, 2021

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

AUTHORITY: §§ 1-5, NRS 639.070 and section 1 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201.

A REGULATION relating to pharmacy; prescribing 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 those drugs by a pharmacist; adopting certain publications by reference; 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)

Section 2 of this regulation requires a pharmacist to complete certain 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 2** also requires a pharmacist who prescribes, dispenses or administers such drugs to maintain and make readily available proof of completion of that course of training. **Section 2** additionally requires such a pharmacist to maintain professional liability insurance coverage of at least $1,000,000.

Section 3 of this regulation requires a pharmacist to complete an assessment of the patient prior to prescribing, dispensing or administering a preexposure prophylaxis drug. **Section 3** authorizes a pharmacist to prescribe, dispense or administer a postexposure prophylaxis drug immediately to a patient exposed to the human immunodeficiency virus and requires the pharmacist to complete an assessment to continue the treatment after the initial dispensing or administering of such a drug. **Section 3** 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 4 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 5** of this regulation requires a pharmacist to comply with those guidelines when prescribing, dispensing and administering drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus. **Section 5** 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 3** under certain circumstances. **Section 5** 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.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 5, inclusive, of this regulation.

Sec. 2. *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, if the pharmacist has completed a course of training concerning treatment using 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, 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, shall maintain professional liability insurance coverage of at least $1,000,000.

Sec. 3. *1. Except as otherwise provided in subsection 2 of section 5 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, 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, 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 5 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, 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 medication;

(b) The proper dosage of the medication;

(c) The effectiveness of the medication;

(d) The potential side effects of the medication;

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

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

(g) The inability of the drug to prevent sexually transmitted infections other that the human immunodeficiency virus.

4. As used in this section:

(a) "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.

(b) "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.

Sec. 4. *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" 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. 5. *1. Except as otherwise provided in subsection 2, a pharmacist shall comply with the publications adopted by reference in section 4 of this regulation 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.*

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 3 of this regulation or the publications adopted by reference in section 4 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 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, 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 4 of this regulation.