REVISED PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R036-21

November 17, 2021

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

AUTHORITY: §§ 1-6, NRS 639.070 and section 2.5 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3268.

A REGULATION relating to contraceptives; establishing a protocol and certain other requirements for a pharmacist to dispense self-administered hormonal contraceptives without a prescription; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Effective January 1, 2022, existing law authorizes a pharmacist to dispense a self-administered hormonal contraceptive to a patient under a protocol established by regulation of the State Board of Pharmacy, regardless of whether the patient has obtained a prescription from a practitioner. Existing law requires a pharmacist to provide a risk assessment questionnaire prescribed by regulation of the Board to a patient who requests a self-administered hormonal contraceptive before dispensing the self-administered hormonal contraceptive to the patient under the protocol. (Sections 2.5 and 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at pages 3268 and 3269) **Section 2** of this regulation requires a pharmacist who wishes to dispense self-administered hormonal contraceptives under the protocol to: (1) complete certain education concerning self-administered hormonal contraceptives; and (2) notify the Board of his or her intent to dispense self-administered hormonal contraceptives under the protocol. **Section 3** of this regulation adopts by reference certain federal guidelines concerning the use of contraceptives. **Section 4** of this regulation prescribes the protocol for a pharmacist to dispense self-administered hormonal contraceptives, which includes: (1) providing the risk assessment questionnaire to the patient and discussing the results with the patient; (2) utilizing a treatment algorithm which includes evaluating the patient using the federal guidelines adopted by reference in **section 3**; (3) providing certain records to the patient; (4) dispensing a self-administered hormonal contraceptive to the patient if it is safe to do so; (5) providing information to the patient concerning use of the contraceptive; (6) the maintenance of certain records by the pharmacy; (7) limitations on the amount of a self-administered hormonal contraceptive that may be dispensed; and (8) certain requirements relating to refills. **Section 5** of this regulation prescribes the risk assessment questionnaire that must be provided to a patient who requests the dispensing of a self-administered hormonal contraceptive under the protocol.

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. Except as otherwise provided in subsection 7 of section 4 of this regulation, a pharmacist who wishes to dispense self-administered hormonal contraceptives under the protocol prescribed in section 4 of this regulation must:***

(a) Complete a course of education concerning self-administered hormonal contraceptives that:

(1) Consists of at least 2 hours of instruction;

(2) Includes, without limitation, instruction concerning the assessment of risks to the patient and contraindications; and

(3) Is approved by the Accreditation Council for Pharmacy Education or the American College of Obstetricians and Gynecologists, or their successor organizations, or provided by a school of pharmacy accredited by the Accreditation Council for Pharmacy Education, or its successor organization; and

(b) Notify the Board of his or her intent to dispense self-administered hormonal contraceptives under the protocol in the form prescribed by the Board.

2. A pharmacist who complies with the provisions of subsection 1 shall maintain in an easily retrievable location a written or electronic record of his or her completion of the course required by paragraph (a) of subsection 1:

(a) While the pharmacist is dispensing self-administered hormonal contraceptives under the protocol prescribed in section 4 of this regulation; and

(b) For at least 2 years after ceasing to dispense self-administered hormonal contraceptives under the protocol.

Sec. 3. *1. Except as otherwise provided in subsection 2, the United States Medical Eligibility Criteria for Contraceptive Use published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services is hereby adopted by reference. A copy of this publication may be obtained free of charge at the Internet address https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html, or, if that Internet website ceases to exist, from the Board.*

2. Except as otherwise provided in this subsection, the most current version of the 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 the publication listed in subsection 1 is appropriate for application in this State. If the Board does not disapprove a change to the publication within 30 days after the review, the change is deemed to have been approved by the Board.

Sec. 4. *1. The protocol prescribed pursuant to section 2.5 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3268, consists of compliance with subsections 2 to 8, inclusive.*

2. Before initially dispensing a self-administered hormonal contraceptive to a patient under the protocol, a pharmacist must:

(a) Provide the patient with the risk assessment questionnaire prescribed in section 5 of this regulation in accordance with subsection 2 of section 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269, and, if the patient completes the questionnaire, discuss the results of the questionnaire with the patient; and

(b) Utilize a treatment algorithm to determine whether it is safe to dispense a self-administered hormonal contraceptive to the patient. The treatment algorithm must include, without limitation:

(1) Training and education of the patient concerning the self-administered hormonal contraceptive and possible alternatives to the self-administered hormonal contraceptive;

(2) Assessing any risks to the patient posed by the self-administered hormonal contraceptive;

(3) Evaluating the patient using the criteria adopted by reference in section 3 of this regulation;

(4) Conducting a health and history screening of the patient;

(5) Screening to determine whether the patient is or may be pregnant;

(6) Screening the patient for disease;

(7) Determining whether the patient is taking other medications and, if so, evaluating the potential interaction between the self-administered hormonal contraceptive and the other medications;

(8) Taking the blood pressure of the patient;

(9) Soliciting and considering the preferences of the patient concerning treatment; and

(10) Formulating a plan for treatment of the patient and discussing the plan with the patient.

3. If, after satisfying the requirements of subsection 2, a pharmacist determines that it is unsafe to dispense a self-administered hormonal contraceptive to the patient, the pharmacist must not dispense the self-administered hormonal contraceptive and must:

(a) Refer the patient to his or her attending provider of health care or another qualified provider of health care for further consultation and treatment; and

(b) Provide the patient with a copy of the record required by subsection 4 of section 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269.

4. If, after satisfying the requirements of subsection 2, a pharmacist determines that it is safe to dispense a self-administered hormonal contraceptive to the patient, the pharmacist must:

(a) Provide the patient with information concerning the self-administered hormonal contraceptive being dispensed, which must include, without limitation, the information described in paragraph (b) of subsection 3 of section 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269, and information concerning:

(1) Proper dosage of the self-administered hormonal contraceptive;

(2) The effectiveness of the self-administered hormonal contraceptive;

(3) The importance of obtaining recommended tests and screening from the attending provider of health care of the patient or another qualified provider of health care who specializes in women's health;

(4) The effectiveness of long-acting, reversible contraceptives as an alternative to self-administered hormonal contraceptives;

(5) When to seek emergency medical services as a result of administering a self-administered hormonal contraceptive; and

(6) The risk of acquiring a sexually transmitted infection and ways to reduce that risk;

(b) Provide the patient with a copy of the record required by subsection 4 of section 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269; and

(c) Dispense an appropriate self-administered hormonal contraceptive to the patient in a container with a label that clearly shows:

(1) The date on which the self-administered hormonal contraceptive was dispensed;

(2) The name and address of the patient;

(3) The serial number assigned to the record of the self-administered hormonal contraceptive in accordance with paragraph (a) of subsection 8;

(4) The number of recommended doses of the self-administered hormonal contraceptive that are being dispensed in the container;

(5) Specific directions for use of the self-administered hormonal contraceptive;

(6) The proprietary or generic name of the self-administered hormonal contraceptive;

(7) The strength of the self-administered hormonal contraceptive; and

(8) The expiration date of the self-administered hormonal contraceptive.

5. A pharmacy that initially dispenses self-administered hormonal contraceptives under the protocol shall maintain:

(a) A written or electronic record of each risk assessment questionnaire completed by a patient of the pharmacy pursuant to paragraph (a) of subsection 2 for at least 2 years after the date of completion; and

(b) The written or electronic record required by subsection 8.

6. A pharmacist who dispenses a self-administered hormonal contraceptive under the protocol shall not dispense to a patient more than a 12-month supply of the self-administered hormonal contraceptive. If the pharmacist initially dispenses to the patient less than a 12-month supply, the pharmacist may refill the self-administered hormonal contraceptive under the protocol until the patient has received a 12-month supply. If the patient requests a refill

after the patient has received a 12-month supply, the pharmacist must comply with the requirements of the protocol set forth in subsections 2, 3 and 4.

7. Subject to the limitations set forth in subsection 6, a pharmacist who has not complied with the requirements of section 2 of this regulation may refill the supply of a self-administered hormonal contraceptive initially dispensed under the protocol if the pharmacist has access to an electronic record of the risk assessment questionnaire completed pursuant to paragraph (a) of subsection 2. When dispensing the refill, such a pharmacist shall:

(a) Review and discuss the results of the risk assessment questionnaire with the patient;

(b) Answer any questions that the patient may have concerning the self-administered hormonal contraceptive; and

(c) Take the actions described in paragraphs (a) and (c) of subsection 4.

8. A pharmacy that dispenses a self-administered hormonal contraceptive under the protocol, including, without limitation, a pharmacy that refills the supply of a self-administered hormonal contraceptive pursuant to subsection 7, shall maintain a written or electronic record of each self-administered hormonal contraceptive dispensed by the pharmacy for at least 2 years after the date on which the self-administered hormonal contraceptive was dispensed. The record must:

(a) Be assigned a serial number;

(b) Include, without limitation, the information required by paragraph (a) of subsection 3 of section 3 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3269; and

(c) Be maintained in the same manner as other records of prescriptions dispensed by the pharmacy.

Sec. 5. ***The risk assessment questionnaire described in paragraph (a) of subsection 2 of section 2.5 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3268, must be in substantially the following form:***

HORMONAL CONTRACEPTIVE RISK ASSESSMENT

QUESTIONNAIRE FOR PATIENT COMPLETION

Note to patient: Complete this questionnaire and bring to your pharmacy for self-administered hormonal contraceptives. You should call your pharmacy first to make certain the pharmacy is able to provide this service. You may also obtain the questionnaire from participating pharmacies.

Patient Name:..... Date:.....

Date of Birth:..... Age:..... Weight:..... Height:.....

Email address:..... Telephone Number:.....

What was the date of your last women's health clinical visit? ___/___/___

Any allergies to medications? Yes □ No □

If yes, list them here:.....

Do you have a preferred method of birth control that you would like to use?

A daily pill □ A weekly patch □ A monthly vaginal ring □ Injectable (every 3 months) □

1	*Do you think you could be pregnant now?*	*Yes* □	*No* □
2	*What was the starting date of your last menstrual period? ___/___/___*		
3	*Have you ever taken birth control pills or used a birth control patch, ring, shot or injection?*	*Yes* □	*No* □
	- If yes, have you previously had contraceptives dispensed to you by a pharmacist?	*Yes* □	*No* □
4	*Have you ever experienced a bad reaction to using hormonal birth control?*	*Yes* □	*No* □
	- If yes, what kind of reaction occurred?		
5	*Are you currently using birth control pills or a birth control patch, ring, shot or injection?*	*Yes* □	*No* □
6	*Have you ever been told by a medical professional not to take hormones?*	*Yes* □	*No* □
7	*Do you smoke cigarettes?*	*Yes* □	*No* □
8	*Have you had a recent change in vaginal bleeding that worries you?*	*Yes* □	*No* □
9	*Have you given birth within the past 21 days?*	*Yes* □	*No* □
	- If yes, what was the date of the birth? ___/___/___		
10	*Are you currently breastfeeding?*	*Yes* □	*No* □
11	*Do you have diabetes?*	*Yes* □	*No* □
12	*Do you get migraine headaches?*	*Yes* □	*No* □
	- If yes, have you ever had headaches that start with warning signs or symptoms, such as flashes of light, blind spots or tingling in your hand or face that goes completely away before the headache starts?	*Yes* □	*No* □
13	*Do you have high blood pressure, hypertension or high cholesterol? (Please indicate yes even if your hypertension is controlled by medication.)*	*Yes* □	*No* □
14	*Have you ever had a heart attack or stroke or been told by a medical professional that you have heart disease?*	*Yes* □	*No* □
15	*Have you ever had a blood clot?*	*Yes* □	*No* □
16	*Have you ever been told by a medical professional that you are at a high risk of developing a blood clot?*	*Yes* □	*No* □
17	*Have you ever had bariatric surgery or stomach reduction surgery?*	*Yes* □	*No* □
18	*Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?*	*Yes* □	*No* □
19	*Do you plan to have restricted mobility for a long period of time? (e.g. a long airplane trip, etc.)*	*Yes* □	*No* □
20	*Do you have or have you ever had breast cancer?*	*Yes* □	*No* □

21	*Do you have or have you ever had hepatitis, liver cancer or gall bladder disease, or do you have jaundice (yellow skin or eyes)?*	*Yes* □	*No* □
22	*Do you have lupus, rheumatoid arthritis or any blood disorders?*	*Yes* □	*No* □
23	*Do you take medication for seizures, tuberculosis (TB), fungal infections or human immunodeficiency virus (HIV)?*	*Yes* □	*No* □
	- If yes, list the medications here:		
24	*Do you have any other medical problems or take regular medication(s)?*	*Yes* □	*No* □
	- If yes, list problems or medications here:		
25	*Do you take any herbal or vitamin supplements?*	*Yes* □	*No* □
	- If yes, list supplements here:		

Patient Signature:..... ***Date:***.....

Reviewing Pharmacist Signature: ..... ***Date:***.....

Sec. 6. This regulation becomes effective upon the later of:

1. January 1, 2022; or

2. The date on which this regulation is filed with the Secretary of State.