PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB FILE NO. R036-21I

The following document is the initial draft regulation proposed

by the agency submitted on 09/08/2021

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – July 15, 2021

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; SB190

A REGULATION relating to contraceptives; establishing a protocol under which a pharmacist may dispense self-administered hormonal contraceptives to any patient; authorizing a pharmacist to dispense self-administered hormonal contraceptives to any patient; and providing other matters properly relating thereto.

NAC Chapter 639 is hereby amended to add new sections to read as follows:

Self-Administered Hormonal Contraceptive Protocol for Pharmacists

1. ***A pharmacist dispensing a self-administered hormonal contraceptive must:***
    a) ***Complete a two (2) hour education course approved by Accreditation Council for Pharmacy Education (ACPE), American College of Obstetricians and Gynecologists (ACOG), or a course offered by an ACPE-accredited pharmacy school regarding self-administered contraceptives, including risk assessment, and contraindications. A record of completion of the required training must be maintained and readily retrievable during the time of dispensing, and for two (2) years after dispensing of self-administered hormonal contraceptive(s) has terminated;***
    b) ***Notify the Board of the Pharmacy that he/she intends to dispense self-administered hormonal contraceptives on a form provided by the Board; and***
    c) ***Follow the protocol in Section 2.***
2. ***If a patient requests a self-administered hormonal contraceptive pursuant to Section 1, then the pharmacist shall:***
    a) ***Have the patient complete a Risk Assessment Questionnaire (RAQ) in Subsection 2(k);***
    b) ***Review the RAQ responses with the patient;***
    c) ***Develop and utilize a treatment algorithm that takes into account training/education, risk assessment, and current United States Medical Eligibility Criteria (USMEC), including the Summary Chart of the USMEC, as formulated by the Centers for Disease Control and Prevention (CDC), which must include, but not limited to:***
        1) ***Health and history screening;***
        2) ***Pregnancy screening;***
        3) ***Disease screening;***
        4) ***Medication screening;***
        5) ***Blood pressure screening;***
        6) ***Patient preference for treatment; and***

7) *Discussion of the treatment plan with the patient.*

d) *If the determination made based upon the algorithm that it is unsafe to dispense, then the pharmacist must:*
   1) *Not dispense the self-administered hormonal contraceptive;*
   2) *Refer the patient to the patient's attending provider or qualified provider of health care;*
   3) *Provide a copy of the completed RAQ; and*
   4) *Provide a copy of the written record of the requested contraceptive.*

e) *If the determination made based upon the algorithm that it is safe to dispense, then the pharmacist shall counsel the patient and provide information on the product dispensed, including, but not limited to:*
   1) *Proper administration and storage of the dispensed contraceptive;*
   2) *Dosage;*
   3) *Effectiveness;*
   4) *Potential side effects;*
   5) *The need to use other methods of contraception, if appropriate;*
   6) *The importance of obtaining recommended tests and screening from the patient's attending provider or another qualified provider of health care who specializes in women's health;*
   7) *The effectiveness of long-acting, reversible contraceptives as an alternative to self-administered hormonal contraceptives;*
   8) *When to seek emergency medical services as a result of administering a self-administered hormonal contraceptive; and*
   9) *The risk of contracting a sexually transmitted infection (STI) and ways to reduce that risk.*

f) *If the pharmacist dispenses a self-administered contraceptive, then the pharmacist shall provide:*
   1) *A copy of the completed RAQ;*
   2) *The written record of the requested contraceptive;*
   3) *The written record of the contraceptive dispensed; and*
   4) *The self-administered contraceptive in a container to which is affixed a label which clearly shows:*
      I. *The date;*
      II. *The name, address, and serial number as required in Section(2)(g)(2);*
      III. *The number of dosage units;*
      IV. *Specific directions for use;*
      V. *The expiration date of the effectiveness of the contraceptive dispensed;*
      VI. *The proprietary or generic name of the contraceptive; and*
      VII. *The strength of the contraceptive.*

g) *The pharmacy shall maintain the following records for two (2) years:*
   1) *A copy of the completed RAQ; and*
   2) *A written serialized numbered record of the self-administered hormonal contraceptive dispensed within the files of prescriptions.*

h) *If the pharmacist dispenses a self-administered contraceptive:*
   1) *A twelve (12) months supply may be dispensed; or*

2) An initial supply may be dispensed with refills up to a twelve (12) months supply.

i) A pharmacist sharing a common electronic database that contains a copy of a patient's RAQ may refill a contraceptive pursuant to Subsection (h)(2) if the pharmacist reviews the RAQ, discusses the RAQ with the patient, answers questions, labels the contraceptive pursuant to Subsection (f)(4), and counsels pursuant to Subsection (e). A pharmacist dispensing a refill pursuant to Subsection (h)(2) does not have to comply with Section 1 of this regulation.

j) An electronic record shall be deemed or constitute a "written record" as applied in Section 2.

k) Risk Assessment Questionnaire form must include, but not limited to, the following in any numerical order:

HORMONAL CONTRACEPTIVE RISK ASSESSMENT QUESTIONNAIRE FOR PATIENT COMPLETION

Note to patient: complete and print out this questionnaire and bring to your pharmacy for self-administered 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 woman'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)* ☐

*Reviewing Pharmacist:*_____ *Date:*_____

1	*Do you think you could be pregnant now?*	*Yes* ☐	*No* ☐
2	*What was the first date of your last menstrual period?* _____/_____/_____		
3	*Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection?*	*Yes* ☐	*No* ☐
	- *Have you previously had contraceptives dispensed to you by a pharmacist?*	*Yes* ☐	*No* ☐
4	*Did you ever experience 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, or shot/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, how long ago?*		
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 comes and 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 it is controlled by medication)*	*Yes* ☐	*No* ☐
14	*Did you ever have a heart attack or stroke, or been told 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	*Did you have 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 four (4) weeks?*	*Yes* ☐	*No* ☐
19	*Will you be immobile for a long period of time? (e.g. planning 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 medications here:*		
25	*Do you take any herbal or vitamin supplements?*	*Yes* ☐	*No* ☐
	- *If yes, list supplements here:*		

*Patient Signature:*_____ *Date:*_____