DEPARTMENT OF HEALTH
BOARD OF PHARMACY
BOARD OF MEDICINE

NOTICE OF PROPOSED RULEMAKING

The Board of Pharmacy and Board of Medicine jointly, pursuant to the authority set forth under Section 208(g-1) of the District of Columbia Health Occupations Revision Act of 1985 ("Act"), effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1202.08(g-1)), as added by Section 2(c) of the Defending Access to Women's Health Care Services Amendment Act of 2018, effective March 28, 2018 (D.C. Law 22-75; 65 DCR 1374), hereby give notice of their intent to adopt the following amendment to Chapter 65 (Pharmacists) of Title 17 (Business, Occupations, and Professionals) of the District of Columbia Municipal Regulations ("DCMR"), in not less than thirty (30) days after the date of publication of this notice in the *District of Columbia Register*.

The rulemaking adds a new Section 6517 (Self-Administered Hormonal Contraceptive Prescriptions) to Title 17 of the DCMR to implement the provisions of the Act which give authority to certain pharmacists to prescribe and dispense self-administered hormonal contraceptives under specific conditions. In accordance with the Act, the Board of Medicine and Board of Pharmacy have jointly developed these regulations.

Chapter 65, PHARMACISTS, of Title 17 DCMR, BUSINESS, OCCUPATIONS, AND PROFESSIONALS, is amended as follows:

A new Section 6517 SELF-ADMINISTERED HORMONAL CONTRACEPTIVE PRESCRIPTIONS, is added to read as follows:

6517 SELF-ADMINISTERED HORMONAL CONTRACEPTIVE PRESCRIPTIONS

6517.1 For the purposes of this section only, the following terms shall have the meanings ascribed:

(a) "Certified pharmacist" means a pharmacist licensed under this Chapter who is certified pursuant to this section to prescribe and dispense up to a twelve (12)-month supply of self-administered hormonal contraceptive.

(b) **"**Protocol" means a document developed by the Boards of Pharmacy and Medicine that provides rules for certified pharmacists to determine if a prescription for a self-administered hormonal contraceptive is medically appropriate using the information provided by the patient in the self-screening questionnaire.

(c) "Self-administered hormonal contraceptive" means a medication to prevent pregnancy containing hormones approved by the U.S. Food and Drug

Administration that is administered by the patient orally, transdermally, or vaginally.

(d) "Self-screening questionnaire" means a document developed by the Boards of Pharmacy and Medicine, based on the current United States Medical Eligibility Criteria for Contraceptive Use developed by the Centers for Disease Control and Prevention, that a patient will use to provide basic information used by a certified pharmacist to determine if a prescription is medically appropriate.

6517.2 A licensed pharmacist may be certified by the Department of Health (the "Department") to prescribe and dispense up to a twelve (12)-month supply of self-administered hormonal contraceptive if the licensed pharmacist:

(a) Possesses a Doctorate in Pharmacy, or

(b) Undergoes a training program approved by the Boards of Medicine and Pharmacy for prescribing and dispensing self-administered hormonal contraceptives.

6517.3 Only pharmacists certified by the Department pursuant to this section are eligible to prescribe and dispense self-administered hormonal contraceptives. Only the certified pharmacist who prescribes the self-administered hormonal contraceptive shall dispense it to the individual for whom it was prescribed.

6517.4 The certified pharmacist shall make information concerning all forms of contraception, including Long-Acting Reversible Contraceptives, approved by the U.S. Food and Drug Administration available to the patient using, at a minimum, the information pamphlet developed by the Board of Pharmacy and the Department before prescribing a self-administered hormonal contraceptive to the patient.

6517.5 The patient shall complete the self-screening questionnaire developed by the Boards of Pharmacy and Medicine, which shall identify patient risk factors for the use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria for Contraceptive Use developed by the Centers for Disease Control and Prevention.

6517.6 The certified pharmacist shall determine if a prescription for self-administered hormonal contraceptives is medically appropriate based on the assessment of the self-screening questionnaire using the protocol developed by the Boards of Pharmacy and Medicine and the duration of the prescription.

6517.7 The certified pharmacist shall obtain the patient's informed consent to the contraceptive to be prescribed before prescribing and dispensing a self-administered hormonal contraceptive to the patient. A person under eighteen (18)

years of age may provide informed consent to the contraceptive pursuant to subsection 22-B DCMR § 600.7.

6517.8 When a self-administered hormonal contraceptive is prescribed and dispensed, the certified pharmacist shall provide the patient, in a manner that ensures patient confidentiality, the following:

(a) Appropriate counseling and information on the product furnished, including dosage, effectiveness, potential side effects, and safety;

(b) Information about the importance of receiving recommended preventative health screenings; and

(c) Counseling that a self-administered hormonal contraceptive does not protect against sexually transmitted infections.

6517.9 Upon prescribing and dispensing a self-administered hormonal contraceptive pursuant to this section, or if it is determined that the use of a self-administered hormonal contraceptive is not recommended, the certified pharmacist shall, using the Hormonal Contraceptive Referral and Visit Summary form developed by the Board of Pharmacy, refer the patient to the patient's primary care provider or reproductive health provider. If the patient does not have a primary care provider or reproductive health provider, the certified pharmacist shall, using the Hormonal Contraceptive Referral and Visit Summary form developed by the Board of Pharmacy, refer the patient to a nearby clinic for continuing health care.

6517.10 In order to obtain a refill of a self-administered hormonal contraceptive prescription from a pharmacist, a patient must verify in the self-screening assessment that a primary care physician or reproductive health provider has examined them within the twelve (12) month period prior to the date of the refill.

6517.11 The certified pharmacist shall maintain records at the pharmacy practice site where the prescription was written and administered in accordance with the requirements of 22-B DCMR § 1913. In addition to the information required pursuant to 22-A DCMR § 1913.4, the records shall include:

(a) The self-screening questionnaire completed by the patient and the certified pharmacist;

(b) The prescription, if the contraceptive was prescribed; and

(c) A copy of the Hormonal Contraceptive Referral and Visit Summary which shall contain the following:

(1) The patient's informed consent to the contraception, if prescribed; and

(2) The referral for continuing health care to either the patient's primary care provider or reproductive health provider, or to a nearby clinic, whichever is applicable.

6517.12 The records required to be maintained pursuant to this section shall be readily available for inspection upon request of the Board of Pharmacy or submitted to the Board of Pharmacy for review upon request.

6517.13 The pharmacy at which the certified pharmacist practices shall display in its stores and online a list of the times during which the certified pharmacist is available.

6517.14 The Board of Pharmacy shall maintain a list of all certified pharmacists, including the location of the pharmacies where the certified pharmacists practice, and shall make the list readily accessible to the public.

6517.15 The Board of Pharmacy shall provide all pharmacists licensed by the District annual notice of the requirements of this section, including opportunities for training.

All persons desiring to comment on the subject matter of this proposed rulemaking action shall submit written comments, not later than thirty (30) days after the date of publication of this notice in the *District of Columbia Register*, to Phillip Husband, General Counsel, Department of Health, Office of the General Counsel, 899 North Capitol Street, N.E., 6th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained between the hours of 8:00 a.m. and 4:00 p.m. at the address listed above, or by contacting Angli Black, Paralegal Specialist, at Angli.Black@dc.gov, (202) 442-5977.