DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Sections 3001O-3003O (16 **Del. C.** §§3001O-3003O)

PROPOSED

PUBLIC NOTICE

4110 Pharmacists Dispensing and Administering Contraceptives

Pursuant to 16 **Del.C.** §§3001O-3003O and 83 Del. Laws, c. 240, the Department of Health and Social Services, Division of Public Health, is proposing new regulation 4110 Pharmacists Dispensing and Administering Contraceptives. This regulation includes requirements, standard procedures, and conditions under which pharmacists may dispense or dispense and administer contraceptives.

Copies of the proposed regulations are available for review in the December 1, 2023 issue of the *Delaware Register of Regulations*, accessible online at: http://regulations.delaware.gov or by calling the Division of Public Health at (302) 744-4951.

Any person who wishes to make written suggestions, testimony, briefs or other written materials concerning the proposed regulations must submit them by the close of business January 2, 2024, at:

Division of Public Health
417 Federal Street
Dover, DE 19901
Email: DHSS_DPH_regulations@delaware.gov

4110 Pharmacists Dispensing and Administering Contraceptives

1.0 Purpose

These regulations are adopted by the Secretary of Delaware Health and Social Services pursuant to 16 **Del.C.** §§3001O-3003O. These regulations establish requirements, standard procedures, and conditions under which pharmacists may dispense or dispense and administer contraceptives.

2.0 Definitions

The following words and terms, when used in this regulation, shall have the following meanings:

"Accreditation Counsel for Pharmacy Education" or **"ACPE"** means the non-profit accreditation national agency recognized by the Council on Higher Education Accreditation and the U.S. Department of Education. The ACPE accredits and pre-accredits schools offering PharmD degrees and providers of continuing pharmacy education.

"Contraceptives" means medications approved by the Food and Drug Administration to prevent pregnancy.

"Healthcare practitioner" means an individual licensed and authorized to write medical orders for an individual under Title 24 of the Delaware Code.

"Injectable hormonal contraceptive" means a medication composed of a hormone or a combination of hormones that is approved by the U.S. Food and Drug Administration to prevent pregnancy and is administered by injection.

"Pharmacist" means an individual licensed under 24 **Del.C.** Ch. 25 to engage in the practice of pharmacy.

"Self-screening tool" means a patient self-assessment questionnaire.

"United States Medical Eligibility Criteria for Contraceptive Use" or **"USMEC"** as issued by the Centers for Disease Control and Prevention, is available at the following link: https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm

3.0 Pharmacist Education and Training

3.1 Prior to dispensing contraceptives or administering injectable hormonal contraception under this regulation, the pharmacist shall have completed education:

3.1.1 Related to dispensing and administering contraceptives, including:

3.1.1.1 Application of the USMEC; and

3.1.1.2 Other guidance on contraception as provided by the Centers for Disease Control and Prevention.

3.1.2 In the form of:

3.1.2.1 A training program offered from an ACPE-accredited provider of continuing pharmacy education; or

3.1.2.2 A curriculum-based training program completed in an ACPE-eligible or ACPE-accredited school of pharmacy.

4.0 Patient Eligibility

4.1 Patients eligible for contraception under this regulation are individuals that are determined to be eligible under 13 **Del.C.** §§707 - 710.

4.2 An individual must confirm that they have seen a healthcare practitioner within 3 years of the initial dispensation or administration of contraception to continue to receive contraception under these regulations.

4.3 Ineligible patients. Patients identified by a pharmacist to be ineligible for contraceptives based on the self-screening tool shall:

4.3.1 Not receive contraception under these regulations;

4.3.2 Be advised why they are ineligible to receive contraception under these regulations; and

4.3.3 Be referred to their health-care practitioner for further evaluation.

5.0 Procedures

5.1 Screening and eligibility

5.1.1 Patients shall be provided with a self-screening tool to complete.

5.1.1.1 A copy of the completed self-screening tool shall be securely stored within the originating pharmacy or healthcare facility for a period of at least 3 years from the date of dispensation or administration of the contraception.

5.1.1.2 The patient shall complete the self-screening tool annually at minimum.

5.1.2 If combined hormonal contraceptives are dispensed, a seated blood pressure measurement is recorded.

5.1.3 A pharmacist shall use the screening tool to determine eligibility for contraceptive use.

5.2 Product selection, dispensation, and administration

5.2.1 The pharmacist, in consultation with the patient, may dispense any non-hormonal contraceptive.

5.2.2 The pharmacist, in consultation with the patient, may dispense any hormonal contraceptive listed in the current USMEC for individuals with:

5.2.2.1 Conditions for which there is no restriction for the use of the contraceptive method ("Category 1"); or

5.2.2.2 Conditions for which the advantages of using the method generally outweigh the theoretical or proven risk ("Category 2").

5.2.3 The pharmacist may administer injectable hormonal contraceptives prescribed by healthcare practitioners or dispensed by a pharmacist.

5.2.4 The pharmacist must dispense the contraceptive or dispense and administer the contraceptive as soon as practicable after the pharmacist determines that the patient meets the requirements under the written standing order created by the Department.

5.3 Information provided to patient. The pharmacist shall provide the patient with:

5.3.1 A record of the encounter, including the patient's self-screening tool;

5.3.2 A record of the contraceptive dispensed or dispensed and administered or the basis for not dispensing or dispensing and administering a contraceptive; and

5.3.3 Written information about the importance of seeing the patient's healthcare practitioner to obtain recommended tests and screenings.

5.4 Referrals and follow-up care. A pharmacist shall refer the patient for appropriate follow-up care to the patient's healthcare practitioner or clinic in the following circumstances:

5.4.1 Upon dispensing a contraceptive to the patient; or

5.4.2 Upon determining ineligibility for contraception.

5.5 Documentation

5.5.1 Each contraceptive dispensed or administered by a pharmacist pursuant to this regulation shall be documented in a patient record and securely stored within the originating pharmacy or healthcare facility for a period of at least 3 years from the dispensed date.

5.5.2 A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under subsection 5.5.1 of this regulation is readily retrievable during the pharmacy's or facility's normal operating hours.

6.0 Severability

If any provision or application of any provision of these regulations is held invalid, that invalidity shall not affect the validity of other provisions or applications of these regulations.

7.0 Penalty

Violators are subject to sanctions pursuant to 16 **Del.C.** §107 for each violation of the requirements established in these regulations.

27 DE Reg. 405 (12/01/23) (Prop.)