Office of the Registrar of Regulations,
Legislative Council,
State of Delaware

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

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

FINAL

ORDER

4110 Pharmacists Dispensing and Administering Contraceptives

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("DHSS"), Division of Public Health ("DPH") initiated proceedings to create new regulation 4110 Pharmacists Dispensing and Administering Contraceptives. These proceedings were initiated pursuant to 29 **Del.C.** Ch. 101 and the authority as prescribed by 16 **Del.C.** §3001O-3003O.

On December 1, 2023 (27 **DE Reg.** 405), DHSS published in the *Delaware Register of Regulations* its notice of this proposed new regulation, pursuant to 29 **Del.C.** §10115. The notice stated that written materials and suggestions from the public concerning the regulation be delivered to DHSS by January 2, 2024, after which time DHSS would review information, factual evidence, and public comment to the said proposed regulations.

SUMMARY OF EVIDENCE:

Comments were received by ChristianaCare, and Highmark Blue Cross Blue Shield Delaware, respectfully.

Comments by Meredith Stewart Tweedie, ChristianaCare:

ChristianaCare appreciates the opportunity to comment on Delaware Division of Public Health (DPH) Proposed Regulation 4110 (the "Proposed Regulation") establishing requirements, standard procedures and conditions under which pharmacists may dispense or dispense and administer contraceptives.

§2.0 Definitions

While the Proposed Regulation defines "Contraceptives" as "medications approved by the Food and Drug Administration to prevent pregnancy," the medical indications of contraceptives are broader than the prevention of pregnancy. It would be helpful for the Proposed Regulation to clarify in more detail whether the scope of practice for pharmacist dispensing of contraceptives is limited to the clinical indication of pregnancy prevention or can also be extended for other clinical uses (as long as such uses are consistent with the USMEC and standard medical and pharmacy best practices).

While the Proposed Regulation also defines and makes multiple references to the "United States Medical Eligibility Criteria for Contraceptive Use" or "USMEC" as issued by the Centers for Disease Control and Prevention1, the website for the USMEC contains multiple links to different iterations of guidance, the most recent version of which appears to have been issued in 2016. It would be helpful for the Proposed Regulation to provide more detail about whether and to what extent the most recent version of the USMEC is intended to govern patient eligibility for this program.

Agency Response: DPH thanks you for your comments. After thoughtful consideration, DPH has decided the published proposed definition of "Contraceptives" will remain unchanged. DPH will indicate the criteria currency in the definition of the USMEC to govern patient eligibility for this program.

§3.0 Pharmacist Education and Training

Proposed Regulation §3.1.1 requires a pharmacist to have completed either "a training program offered from an ACPE-accredited provider of continuing education, or a curriculum-based training program completed in an APCE-eligible or APCE-accredited school of pharmacy." It would be helpful for the Proposed Regulation to clarify whether there is a minimum threshold for the number of training hours required for completion of a program that satisfies the requirements of §§ 3.1.2.1. and 3.1.2.2 and/or clarify that a minimum of two (2) compliant training program hours is sufficient to satisfy this requirement.

For purposes of awareness, clarity and facilitating compliance, we respectfully recommend that the Proposed Regulation is revised to be structured in a manner that is more consistent, to the fullest extent practicable, with the Board of Pharmacy's existing requirements relating to the administration and dispensing of immunizations, in particular the requirements relating to continuing education, documentation, consent, and maintenance of records.

Agency Response: DPH thanks you for your comments. After thoughtful consideration, DPH has decided that no changes will be made to this section at this time.

4.0 Patient Eligibility

Proposed Regulation §4.1 provides that "patients eligible for contraception under this regulation are individuals that are determined to be eligible under 13 **Del.C.** §§707 - 710."

The above-referenced provisions in the Delaware Code, 13 **Del. C.** §§ 707 - 710, relate to the legal requirements for consent to health care treatment of minors, which makes it appear as if the Proposed Regulation limits eligibility for the

pharmacy-based contraceptive dispensing program exclusively to minors. We respectfully request clarification of the eligibility language in Section 4.0 of the Proposed Regulation.

Section 709 relates to the consent requirements for a minor to donate blood and does not appear to have anything to do with the prescribing or dispensing of contraceptives. Accordingly, for purposes of clarity, we respectfully recommend striking the reference to 13 **Del. C.** § 709.

It would also be helpful for the Proposed Regulation to more specifically address the expectations of pharmacists to comply with the provisions of Section 707 (Consent to health care of minors), Section 708 (Affidavit of Establishment of Power to Relative Caregivers to Consent to Medical Treatment of Minors) and 710 (Minors' consent to diagnostic and lawful therapeutic procedures relating to care and treatment for pregnancy or contagious diseases).

Proposed Regulation §4.2 states that "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." As noted in the above comments to §2.0, the Proposed Regulation to clarify in more detail the specific requirements relating to patient eligibility, including the following:

- "Whether pharmacist dispensing authority and program eligibility extends to patients who have not previously been prescribed contraceptives;
- "Whether a patient remains continuously eligible for contraceptive access and dispensing after providing the required initial verification of having seen a primary care physician within the previous three years.

Agency Response: DPH thanks you for your comments, and is responding in the order provided below:

- "DPH will adjust the patient eligibility language to include, "Patients eligible for contraception under this regulation are **[adults and]** individuals who are determined to be eligible under the Delaware Code, 13 Del. C. §§ 707 - 710." After thoughtful consideration, DPH has decided that no changes will be made to the citing of the Delaware code.
- "After thoughtful consideration, DPH has decided that no changes will be made to more precisely address specific expectations of pharmacists to comply at this time.
- "After thoughtful consideration, DPH has decided that no changes will be made to § 4.2 at this time.

§5.0 Procedures

Proposed Regulation §5.1.1 requires patients to complete a self-screening tool on an annual basis (at a minimum) in order to receive contraceptives at a pharmacy. We respectfully request that a template screening tool should be developed by DPH in collaboration with the Delaware Board of Pharmacy. The Maryland Board of Pharmacy has a comprehensive assessment tool that is used statewide that could potentially be used as a template for Delaware.

Thank you again for the opportunity to comment on the Proposed Regulation.

Agency Response: DPH thanks you for your comments and appreciates this suggestion, however, DPH will not be developing the screening tool. While DPH will not develop the screening tool required to be used for these services, there are many screening tools already developed that meet the requirements of these regulations and will be shared by DPH during implementation.

Comments by Tija R. Hilton-Phillips, Highmark Inc.:

Thank you for the opportunity to provide comments on Proposed Regulation 4110: Pharmacists Dispensing and Administering Contraceptives. Highmark Blue Cross Blue Shield Delaware offers the following comments for consideration:

Section 4.1 of the regulation states that "[p]atients eligible for contraception under this regulation are individuals that are determined to be eligible under 13 **Del. C.** §§707-710." However, 13 **Del. C.** §§707-710 addresses consent to health care of minors and related matters so this section, as written, could be interpreted to mean that only minors with the required consent in place are eligible for contraception under the regulation. Please clarify whether that is the Department's intent. If the Department's intent is that both adults and individuals that are determined to be eligible under 13 **Del. C.** §§707-710 are patients eligible for contraception under this regulation, then we suggest that this section of the regulation be amended as follows: "Patients eligible for contraception under this regulation are adult individuals and individuals who are determined to be eligible under 13 **Del. C.** §§707-710."

Agency Response: DPH will adjust the patient eligibility language to include, "Patients eligible for contraception under this regulation are adults and individuals who are determined to be eligible under the Delaware Code, 13 **Del. C.** §§707 - 710."

Section 4.2 requires an individual to "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." However, the regulation does not appear to require the patient to confirm that they have received counseling from a healthcare practitioner related to contraception specifically. Without such counseling from a healthcare practitioner prior to initial dispensation or administration of contraception, the patient may not be aware of the risks associated with contraception or the recommended screenings, tests, or services. For example, screening regarding sexual activity, testing for sexually transmitted diseases, pelvic exams, and pap smears. Another example is the need for a hypercoagulability work up.

Agency Response: DPH thanks you for your comments. After thoughtful consideration, DPH will not be including this recommendation but has made other technical changes to both subsections 4.1 and 4.2, as indicated in the above response

Section 5.1.1 requires patients to be provided with a self-screening tool to complete. It is unclear from the regulation

what questions will be included in the self-screening tool and how those questions will be developed.

Agency Response: DPH thanks you for your comments and appreciates this suggestion, however, DPH will not be developing the screening tool. DPH thanks you for your comments and appreciates this suggestion, however, DPH will not be developing the screening tool. While DPH will not develop the screening tool required to be used for these services, there are many screening tools already developed that meet the requirements of these regulations and will be shared by DPH during implementation.

Section 5.1.2 requires that "[i]f combined hormonal contraceptives are dispensed, a seated blood pressure management is recorded." However, a seated blood pressure management recording alone may not be sufficient to assess a patient's health and any potential safety risks with combined hormonal contraceptives for a particular patient. For example, if a patient has a family history of blood clots, other tests may be needed before dispensing combined hormonal contraceptives. Or, if a patient has a history of smoking, the counseling regarding non-hormonal contraception may be appropriate.

Agency Response: DPH thanks you for your comments. After thoughtful consideration, DPH has decided that no changes will be made to subsection 5.1.2.

Section 5.1.3 states that "[a] pharmacist shall use the screening tool to determine eligibility for contraceptive use." However, it is unclear from the regulation under what circumstances a patient will be considered ineligible based on the answers reported in the self-screening tool. In addition, it does not appear as though there will be any verification with a patient's healthcare practitioner of the answers reported in the self-screening tool. Consideration should be given to verifying the information reported in the self-screening tool for safety reasons. For example, if smoking status is included in the self-screening tool and a patient inaccurately reports such status, that could pose a patient safety risk.

Agency Response: DPH thanks you for your comments. After thoughtful consideration, DPH has decided that no changes will be made to subsection 5.1.3.

Section 5.2.4 of the regulation refers to a "written standing order created by the Department." Can the Department address when a written standing order will be created and what, if any stakeholder review and comment will be solicited.

Agency Response: DPH thanks you for your comments. The standing order is complete and has been signed by the DPH Medical Director. There are no requirements for public comment.

Finally, please note that without knowing the contents of the self-screening tool referred to in section 5.1.1 and the written standing order referred to in section 5.2.4, it is difficult to assess whether patients will be adequately protected by this proposed regulation.

Agency Response: DPH acknowledges and appreciates your comments but has determined that no changes will be made to subsections 5.1.1 or 5.2.4.

Thank you for the opportunity to review and provide comments.

FINDINGS OF FACT:

Technical changes were made to the regulation since publication as proposed. DHSS finds that the proposed regulation, as amended and set forth in the attached copy, should be adopted in the best interest of the public of the State of Delaware.

THEREFORE, IT IS ORDERED, that proposed new regulation 4110 Pharmacists Dispensing and Administering Contraceptives is hereby adopted and shall become effective February 11, 2024 (ten days), after publication of the final regulation in the *Delaware Register of Regulations*.

1/25/2024 | 12:29 PM EST
Date

Josette D. Manning, Esq.
DHSS Cabinet Secretary

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~~ Council] 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 **[in its current version]** 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~~ by]** 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 **[adults and]** individuals that are determined to be eligible under 13 **Del.C.** §§707 - 710.

4.2 **[~~An individual~~ A patient]** must **[~~confirm that they have~~ attest to having]** 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 **[of Health and Social Services]**.

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. 609 (02/01/24) (Final)