WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES BUREAU FOR PUBLIC HEALTH

OFFICE OF THE COMMISSIONER & STATE HEALTH OFFICER

STANDING ORDER HORMONAL CONTRACEPTION PRESCRIPTION TO AVOID UNINTENDED PREGNANCY

I. PURPOSE

This standing order is intended to ensure that residents of the State of West Virginia have ease of access to self-administered hormonal contraceptive methods. In West Virginia, nearly 38% of all pregnancies are unintended (Guttmacher 2014; WV Department of Health and Human Resources (DHHR) Prenatal Risk Screening Instrument, 2018). Some subpopulations of women experience much higher rates of the same. Unplanned pregnancy is associated with an increased risk of problems for the mother and baby. The rurality of the state, with little to no public transportation available in many areas, is often cited as a barrier to accessing health care for many of the state's residents. In addition, clinic hours, work schedules, childcare, the need to preschedule appointments, etc. can all impact this issue. Allowing expanded access will give women the opportunity to obtain contraceptive methods more easily, thus helping them to plan the timing and spacing of their families and reduce unintended pregnancy.

II. SCOPE

This standing order applies to licensed pharmacists in the State of West Virginia who have completed the necessary training and certification, and are enrolled for the program with the West Virginia Board of Pharmacy (BOP) as outlined in Section IV.

This order is not intended to be used by organizations who employ or contract with medical staff who are authorized to write prescriptions. Organizations with a medical staff should rely on those medical professionals to write prescriptions or issue standing orders specific to the personnel who would be expected to administer or dispense hormonal contraceptive methods within or through these organizations.

III. AUTHORITY

This standing order is issued pursuant to the Family Planning Access Act of 2019, codified at article 58 of chapter 16 of the West Virginia Code, which permits the State Health Officer, on a statewide basis, to prescribe self-administered hormonal contraception according to the requirements of this standing order.

A pharmacist assessing patients and dispensing self-administered hormonal contraception must follow the enrollment, dispensing, educational, record maintenance, and reporting requirements specified in this standing order.

IV. ENROLLMENT OF PHARMACISTS

Pharmacists who plan to dispense hormonal contraception under this standing order are required to enroll with the BOP and complete training and certification approved by the BOP and DHHR. Pharmacists will be required to maintain certification as mandated by the BOP.

V. CONTRACEPTIVE COUNSELING

Quality contraceptive counseling by the enrolled pharmacist in accordance with program training is a critical and required component of this standing order. Information and education must be provided on a full range of methods, including those beyond the self-administered hormonal contraceptives covered by this standing order. Contraceptive options, including those dispensed under this standing order, must be made available to patients on a voluntary basis, without coercion.

VI. DISPENSING GUIDELINES

Any person age 18 and over may receive self-administered hormonal contraception under this standing order provided a self-assessment tool has been completed and the method is deemed medically appropriate by the enrolled pharmacist in accordance with the Centers for Disease Control and Prevention's (CDC) U.S. Medical Eligibility Criteria guidelines. If the enrolled pharmacist's review of the patient self-assessment questionnaire indicates the patient's preferred method is unsafe, they should not dispense the contraceptive method and refer the patient to a physician or other applicable health care provider. If an enrolled pharmacist is not onsite, dispensing may not occur.

If the assessment indicates that it is safe to dispense hormonal contraception to the patient, the enrolled pharmacist has the authority to provide it. Self-administered hormonal contraceptive methods chosen and dispensed under this standing order must be approved by the US Food and Drug Administration (FDA) to prevent pregnancy and include *only* the following:

- Oral hormonal contraceptive;
- · Hormonal vaginal ring; and
- Hormonal contraceptive patch.

VII. FORMULATION AND DIRECTIONS

Enrolled pharmacists may dispense an initial three-month supply of the above self-administered hormonal contraceptives. Refills for up to a total of 12 months may be provided upon verification from the patient that she has consulted with her health care provider following receipt of the initial supply of self-administered hormonal contraceptives. All patients must be linked at least annually back to a health care provider able to provide recommended, age appropriate reproductive and other preventive health services and screenings.

Prior to the provision of refills beyond the initial 3-month supply, an evaluation is required for assessment of patient compliance with the given method, assessment of side effects, provision of education, and at least patient verbal verification of consultation with her health care provider. The three-month evaluation can be completed by phone with the patient. Patient evaluations must occur at a minimum of every 12 months for continuation of the pharmacist-prescribed hormonal contraceptive. At each annual evaluation, a new self-assessment tool must be completed by the patient to ascertain any changes in medical history or interest in changing methods, etc. If a patient provides information upon which an enrolled pharmacist determines that a self-administered hormonal contraceptive is no longer appropriate or desired, or the patient does not provide evidence of consulting with a practitioner for routine reproductive health screenings and services as required (evidence can include a self-attestation), the enrolled pharmacist shall not continue to dispense the self- administered hormonal contraceptive to the patient under this protocol.

VIII. EDUCATIONAL MATERIALS

Every patient receiving a self-administered hormonal contraceptive must receive written information on the following, and be counseled on the same, from their pharmacist at initial dispensing:

- A copy of the record of the encounter that includes the patient's completed self- assessment tool and a description of the contraceptives dispensed, or the basis for not dispensing a contraceptive;
- Instructions for using the chosen self-administered hormonal contraceptive, including medication storage, common side effects, contraceptive efficacy, need for back up contraception, and when to seek medical attention;
- The importance of prevention of sexually transmitted infections and ways to reduce the risk of contracting a sexually transmitted infection;
- The importance of seeing the patient's primary care provider or reproductive health care
 provider at least annually to obtain age-appropriate recommended tests and screenings as
 outlined by the American College of Obstetrics and Gynecology (ACOG) and others;
- The effectiveness and availability of all types of contraceptives, including long-acting reversible contraceptives in addition to self-administered hormonal contraceptives.

Educational materials provided should be objective, vetted and reviewed by professionally recognized experts (e.g., ACOG, CDC, AAFP, HHS, FDA).

IX. REFERRALS

If the enrolled pharmacist deems the hormonal contraceptive medication inappropriate to prescribe based on the self-assessment tool or counseling provided, the patient should be given a copy of the encounter with the reason why the medication could not be prescribed. Referral should be made to the patient's primary care provider, or other reproductive health care provider or local family planning clinic if the patient is not established elsewhere. Educational material as above should also be provided including information on long-acting reversible contraceptives and prevention of sexually transmitted diseases. Referral to a tobacco cessation program and for necessary immunizations should also be considered and provided, as applicable.

Adolescents under the age of 18 seeking contraceptive services from pharmacists can be provided education as above on contraceptive methods and sexually transmitted infection prevention. Patients under the age of 18 should be referred to a primary care provider or a local family planning clinic offering confidential reproductive health care services.

X. REVIEW

This standing order will be reviewed and may be updated if there is relevant new science about hormonal contraceptive methods or administration, lessons learned from its application, or at least in two years.

This standing order may be revised or withdrawn at any time with notification to the BOP. EXECUTED on this the _____ day of ____ 20___.

Dr. Mark E. McDaniel, DO, FAAFP

TITL

Acting State Health Officer WV Department of Health