Indiana Department of Health

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# Indiana Protocol for Pharmacists Dispensing Hormonal Contraceptive Patches and Self-Administered Hormonal Contraception under Statewide Standing Order

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Pursuant to Indiana Code 16-19-4-12, the State Health Commissioner issued a Statewide Standing Order for Hormonal Contraceptive Patches and Self-Administered Hormonal Contraception (the Statewide Standing Order) which authorizes qualified pharmacists to dispense Food and Drug Administration (FDA)- approved medications with an indication for pregnancy prevention and that may be self-administered by the person to whom it is prescribed, in accordance with this Protocol. This Protocol is to be used in conjunction with the Statewide Standing Order.

## A. PURPOSE

This protocol specifies the criteria and procedures to assist pharmacists in providing safe and effective hormonal contraception therapy in Indiana.

## B. QUALIFICATIONS

To operate under the Statewide Standing Order, the pharmacist must:

1. Have an active Indiana pharmacist license pursuant to Indiana Code 25-26-13;
2. Have received education and training in pregnancy prevention and hormonal contraceptives; and
3. Be acting in good faith and exercising reasonable care.

## C. PRODUCTS COVERED

Notwithstanding any other provision of law, a pharmacist may dispense any FDA-approved medication that contains a hormone or combination of hormones with an indication for pregnancy prevention that may be self-administered by the person to whom it is prescribed. A drug, substance, or device that contains a progesterone receptor antagonist is excluded.

**D. PROCEDURES**

When a patient requests a medication for contraception, or when a pharmacist in his or her professional judgment decides to ask about pregnancy prevention and offer to initiate contraception counseling and treatment, the pharmacist shall complete the following steps, which may be reviewed and revised as necessary by the Indiana State Department of Health or when the Statewide Standing Order is reissued:

1. Determination of Eligibility:
    a. The pharmacist may offer self-administered hormonal contraceptives to those who are eligible based on the following:
        i. Aged 18 years or older; and
        ii. Have received no more than a total of a 12-month supply of a hormonal contraceptive from a pharmacist previously without evaluation by a provider (e.g.; primary care provider, women's health provider, etc.).
2. Assessment:
    The pharmacist shall ensure that the pharmacy provides appropriate space to prevent the spread of infection and ensure confidentiality. Refer to Standard Procedures Algorithm (Appendix A). The pharmacist should utilize the U.S. Selected Practice Recommendations for Contraceptive Use and U.S. Medical Eligibility Criteria for Contraceptive Use to guide the assessment and plan for the patient.

    a. For each new patient requesting contraception, and at least every six months for each returning patient, obtain a completed self-screening risk assessment questionnaire (see Appendix B for a checklist of conditions for which to screen and Appendix C for an example of a questionnaire) from the patient before dispensing the self-administered hormonal contraceptive. If the results of the assessment indicate that it is unsafe to dispense a self-administered hormonal contraceptive, based on the U.S. Medical Eligibility Criteria for Contraceptive Use, the pharmacist shall refer the patient to a practitioner, and may not continue to dispense a self-administered hormonal contraceptive to the patient.
    b. For each new patient requesting contraception, and at least every six months for each returning patient, assess the patient's blood pressure before dispensing the self-administered hormonal contraceptive. If the systolic blood pressure is > 140 or diastolic blood pressure > 90 mmHg, the pharmacist may prescribe a progestin-only self-administered hormonal contraceptive, as per the Summary

Chart of US Medical Eligibility Criteria for Contraceptive Use (USMEC). If the results of the blood pressure assessment indicate that it is unsafe to prescribe or dispense an estrogen-containing self-administered hormonal contraceptive, the pharmacist shall refer the patient to a practitioner, and may not continue to dispense an estrogen-containing self-administered hormonal contraceptive to the patient.

c. Upon prescribing a self-administered hormonal contraceptive, the pharmacist shall refer the patient to a primary care practitioner or women's health care practitioner.
d. If the pharmacist works at a site that has a physician, advance practice registered nurse, or physician assistant who is available to deliver patient care and is capable of prescribing the hormonal contraceptive patch or self- administered hormonal contraceptive, the prescribing pharmacist may suggest that the patient see the provider.
e. If the pharmacist deems the hormonal contraceptive medication inappropriate to dispense based on the self-assessment tool and as indicated by the USMEC, the patient should be given an electronic or written copy of the encounter, with the reason why the medication could not be dispensed. 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.

3. Dispensing Eligible Products:
    a. The pharmacist may prescribe and dispense any FDA-approved hormonal contraceptive that meets the criteria in this protocol and standard procedures algorithm for individuals identified as Category 1 or 2 from the current USMEC (Appendix D).
    b. The pharmacist may prescribe and dispense a self-administered hormonal contraceptive for a period of time not to exceed six months initially. A second six-month supply may be prescribed if the patient is reassessed.
    c. The pharmacist may not continue to dispense a self-administered hormonal contraceptive to the patient for more than 12 months after the date of the initial prescriptions without evidence that the patient has consulted with a provider during the preceding 12 months.
    d. The pharmacist shall provide a written record of the contraceptive prescribed and advise the patient to consult with a primary care practitioner or women's health care practitioner. This record may be an electronic or paper copy.

4. Counseling:
    a. Once the appropriate self-administered hormonal contraceptive has been determined, the pharmacist shall provide the patient with counseling about the therapy. Counseling may include, but is not limited to:
        i. The name and description of the medicine.
        ii. The route, dosage form, dosage, and route of administration.
        iii. Special directions and precautions.
        iv. Common adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.
        v. Techniques for self-monitoring drug therapy.
        vi. Proper storage.
        vii. Prescription refill information.
        viii. Action to be taken in the event of a missed dose.
        ix. The need for backup contraception.
        x. When to seek emergency medical attention.
    b. Additional counseling by the pharmacist may include, but is not limited to:
        i. The importance of seeing the patient's practitioner annually to obtain recommended tests and screening.
        ii. The effectiveness and availability of long-acting reversible contraceptives as an alternative to hormonal contraceptive patches or self-administered hormonal contraceptives.
        iii. That hormonal contraceptive patches and self-administered hormonal contraceptives do not protect against sexually transmitted infections (STIs).
    c. A patient experiencing side effects should be referred to a primary care or women's health provider for further evaluation and treatment.

## E. NOTIFICATION

The pharmacist must provide the patient with a record of the drug(s) prescribed and dispensed and inform the patient to follow-up with their primary care provider or women's health provider.

## F. DOCUMENTATION

1. Documentation of the assessment and plan of a patient shall be maintained in the records for seven years in accordance with Indiana Code 16-39-7-1.
2. A copy shall be made available to the patient and/or patient's provider upon request.