

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-15
PRESCRIBING AND DISPENSING OF HORMONAL CONTRACEPTIVES**

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1140-15-.01 PURPOSE. A pharmacist is authorized to prescribe hormonal contraceptives, in good faith, pursuant to a valid collaborative pharmacy practice agreement which contains a nonpatient-specific prescriptive order and standardized procedures developed and executed by one (1) or more authorized prescribers.

Authority: T.C.A. § 63-10-219. **Administrative History:** Original rules filed April 19, 2018; effective July 18, 2018.

1140-15-.02 DEFINITIONS.

- (1) "Hormonal contraceptive" means a self-administered drug, or a transdermal patch applied to the skin of a patient, by the patient or by a pharmacist, which releases a drug composed of a combination of hormones that are approved by the United States Food and Drug Administration ("FDA") to prevent pregnancy.
- (2) "Total cost" means the specific information regarding the cost of the hormonal contraceptive and the fee charged by the pharmacist for the administration, application, or any other patient care service provided to the patient by the pharmacist.
- (3) "Pharmacist's agent" means an individual, such as a registered pharmacy technician, pharmacy clerk, or pharmacy intern, working under the supervision of a pharmacist who is authorized to assist in tasks and responsibilities related to the delivery of patient care services pursuant to a valid collaborative pharmacy practice agreement.

Authority: T.C.A. § 63-10-219. **Administrative History:** Original rules filed April 19, 2018; effective July 18, 2018.

1140-15-.03 TRAINING.

- (1) Each pharmacist licensed in the state of Tennessee shall complete educational training pertaining to the prescribing of hormonal contraceptives prior to providing contraceptive therapies to patients pursuant to this rule. This rule does not prohibit pharmacists from providing care and services to patients, including hormonal contraceptives, pursuant to a valid patient-specific collaborative pharmacy practice agreement.
- (2) The minimum required educational training shall be approved by the Tennessee Department of Health ("TDH"), listed on the TDH website, and provided by an Accreditation Council for Pharmacy Education ("ACPE") -approved provider.
- (3) The pharmacist shall permanently maintain the certificate of completion of training at their place of practice and shall make the certificate of completion available to the Board of Pharmacy upon request.

(Rule 1140-15-.03, continued)

- (4) The training program shall provide, at a minimum, information pertaining to the types and pharmacology of hormonal contraceptives which may be prescribed, the risk and benefits of each hormonal contraceptive, any side effects associated with the hormonal contraceptive, and any contraindications associated with the hormonal contraceptive.

The training program shall provide the prescribing pharmacist with a minimum level of proficiency regarding proper prescribing of hormonal contraceptives.

- (5) An equivalent curriculum-based training program completed in or after the year 2017 from a school or college of pharmacy recognized by the Board or a training program recognized by the Board shall satisfy the requirement of training prior to the prescribing of hormonal contraceptives.
- (6) It shall be the professional responsibility of each pharmacist engaged in the prescribing of hormonal contraceptives to maintain current knowledge regarding the science and trends of hormonal contraceptives.

Authority: T.C.A. § 63-10-219. **Administrative History:** Original rules filed April 19, 2018; effective July 18, 2018.

1140-15-.04 COLLABORATIVE PHARMACY PRACTICE AGREEMENTS. Within 30 days from the effective date of a collaborative pharmacy practice agreement, the prescribing pharmacist shall submit written attestation to the Board for the purpose of notifying the Board of the collaborative agreement.

Authority: T.C.A. §§ 63-10-217 and 63-10-219. **Administrative History:** Original rules filed April 19, 2018; effective July 18, 2018.

1140-15-.05 DELIVERY OF CARE. A pharmacist may provide hormonal contraceptives under this rule to eligible individuals as identified in T.C.A. § 63-10-219.

Authority: T.C.A. §§ 39-11-106 and 63-10-219. **Administrative History:** Original rules filed April 19, 2018; effective July 18, 2018.

1140-15-.06 PROCEDURAL MANDATES. For each new patient requesting a hormonal contraceptive, and, at a minimum of every twelve months for each returning patient, the prescribing pharmacist shall:

- (1) Ask the patient to use and complete the TDH-produced standardized self-screening risk assessment tool. The TDH-produced standardized self-screening risk assessment tool shall be the only self-screening risk assessment tool to be utilized when evaluating a patient's candidacy for a hormonal contraceptive. The TDH-produced standardized self-screening risk assessment tool shall be made available through the TDH website. The same TDH-approved standardized self-screening risk assessment tool may be incorporated into a pharmacy's management system's software.
- (2) Review the self-screening risk assessment answers and clarify responses with the patient as needed before using professional judgment regarding whether to prescribe a hormonal contraceptive.
- (3) Dispense a hormonal contraceptive to the patient or refer the patient to a pharmacy that may dispense the hormonal contraceptive, if the pharmacist determines the patient is eligible to receive the medication.

Dispensing a hormonal contraceptive or referring the patient to another pharmacy that may dispense a hormonal contraceptive shall occur as soon as practicable after making the determination that the patient is eligible to receive a hormonal contraceptive.

(Rule 1140-15-.06, continued)

- (4) Counsel the patient on matters contained in Tenn. Comp. R. & Regs. 1140-03-.01(1)(e)1 through 1140-03-.01(1)(e)8 at the time the hormonal contraceptive is prescribed and dispensed.
- (5) Provide the patient with the FDA-required patient product information document that is included with the hormonal contraceptive and a factsheet which includes, but is not limited to, the indications and contraindications for the use of the drug, the appropriate method for using the drug, the importance of a medical follow-up, and other appropriate information.
- (6) Advise the patient to consult with the patient's primary care practitioner or women's health practitioner.
- (7) Provide the patient, at the time the hormonal contraceptive is prescribed, with a list which contains contact information for primary care practitioners or women's health practitioners. In the event it is not practicable to provide contact information at the time the hormonal contraceptive is prescribed, the prescribing pharmacist shall provide contact information for primary care practitioners or women's health practitioners within seventy-two (72) hours after the contraceptive is prescribed.

Authority: T.C.A. § 63-10-219. **Administrative History:** Original rules filed April 19, 2018; effective July 18, 2018.

1140-15-.07 PROHIBITED PRACTICES. A prescribing pharmacist shall not require the patient to schedule an appointment with the pharmacist for the purpose of prescribing or dispensing of a hormonal contraceptive. However, nothing in this rule shall prevent a pharmacist from providing services which are incorporated into normal flow of business in order to promote efficiency and to optimize patient care.

Authority: T.C.A. § 63-10-219. **Administrative History:** Original rules filed April 19, 2018; effective July 18, 2018.

1140-15-.08 RECORDS.

- (1) The prescribing pharmacist shall document, at a minimum, the completed self-screening risk assessment and the medication prescribed to the patient by the pharmacist. While not required by this rule, the pharmacist is authorized to include additional information related to the patient encounter. These records shall be maintained by the pharmacy practice site for a period of ten years.

Records regarding the dispensed hormonal contraceptive shall be maintained in accordance with Tenn. Comp. R. & Regs. 1140-03-.03.

Authority: T.C.A. § 63-10-219. **Administrative History:** Original rules filed April 19, 2018; effective July 18, 2018.

1140-15-.09 FEES.

- (1) A pharmacist, pharmacist's employer, or pharmacist's agent is authorized to charge an annual administrative fee for services provided to patients pursuant to this Chapter in addition to any costs associated with the dispensing of the drug. However, patients who are insured or covered and receive a pharmacy benefit that covers the cost of hormonal contraceptives shall not be required to pay an administrative fee; instead, these patients shall be required to pay co-payments pursuant to the terms and conditions of their coverage.

(Rule 1140-15-.09, continued)

- (2) Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total cost that a consumer would pay for pharmacist-provided hormonal contraceptives.
- (3) The "total cost" requirement is not intended to interfere with patients who have active hormonal contraceptive coverage under an insurance plan or pharmacy benefit which has been contractually agreed upon between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health insurance plan or insurer.

Authority: T.C.A. § 63-10-219. **Administrative History:** Original rules filed April 19, 2018; effective July 18, 2018.