

Adopt Ph 2400 to read as follows:

CHAPTER Ph 2400 PHARMACIST INITIATION AND DISPENSING OF HORMONAL CONTRACEPTIVES

PART Ph 2401 DEFINITIONS

Ph 2401.01 Definitions.

(a) “Hormonal contraceptives” means pills, patches, and rings which the United States Food and Drug Administration (FDA) classifies as available by prescription for the purpose of contraception or emergency contraception. It does not include similar items classified as “over the counter” by the FDA, intrauterine devices, shots or intradermal implants.

(b) “Standing order” means a written and signed protocol authored by one or more physicians licensed under RSA 329:12 or one or more advanced practice registered nurses licensed under RSA 326-B:18. Such agreement shall specify a protocol allowing the pharmacist licensed under RSA 318:18 to dispense hormonal contraceptives under the delegated prescriptive authority of the physician or APRN, specify a mechanism to document screening performed and the prescription in the patient’s medical record, and include a plan for evaluating and treating adverse events. Any such prescription shall be regarded as being issued for an approved medical purpose in the usual course of professional practice.

(c) “Licensed pharmacist” or “pharmacist” means “licensed pharmacist” or “pharmacist” as defined in RSA 318:1, VII, namely, “when not otherwise limited, means a person holding a license under RSA 318:18 and who is, therefore legally authorized to practice the profession of pharmacy in this state.”

(d) "Board" means the New Hampshire board of pharmacy created by RSA 318.

(e) “Model statewide protocol” means a protocol for dispensing hormonal contraceptives in pursuant of RSA 318:47-1 jointly developed by the Board of Medicine, the Board of Nursing, and the Department of Health and Human Services.

(f) “New Hampshire Self Screening Risk Assessment Questionnaire” means a Board-approved screening tool utilized by a licensed pharmacist to assess whether to dispense a hormonal contraceptive via standing order.

(g) “Practitioner” or “licensed practitioner” means “practitioner” or “licensed practitioner” as defined in RSA 318:1, XV, namely, “means any person who is lawfully entitled to prescribe, administer, dispense, or distribute legend drugs to patients.”

(f) "Outpatient contraceptive services" means hormonal contraceptive prescribing and dispensing services provided by the licensed pharmacist as specified in RSA 318:47-1.

(g) “Clinical Visit” means a consultation with a healthcare practitioner, other than a pharmacist, for women’s health, which should address contraception and age-appropriate screening.

(h) “Standard algorithm” means an algorithm developed based upon the following select procedures and recommendations, as adopted by the U.S. Centers for Disease Control and Prevention:

- (1) U.S. Medical Eligibility Criteria (MEC) for Contraceptive Use;
- (2) U.S. Selected Practice Recommendations (SPR) for Contraceptive Use; and
- (3) Any other Accreditation Council for Pharmacy Education (ACPE) and board-approved protocols for contraceptive use.

PART Ph 2402 PURPOSE, SCOPE, AND COOPERATION

Ph 2402.01 Purpose. The purpose of this section is to promulgate procedures regarding the dispensing of oral contraceptives, via a standing order, pursuant to RSA 318:47-1.

Ph 2402.02 Scope. The rules shall regulate pharmacists licensed by the New Hampshire board of pharmacy in the prescribing and dispensing of hormonal contraceptives without a prior prescription.

Ph 2402.03 Cooperation. In order to clarify, improve, and support appropriate pharmacist prescribing, the board shall periodically review prescribing standards and practices and seek recommendations in consultation with designated representatives from the New Hampshire board of medicine, New Hampshire board of nursing, and the department of health and human services.

PART Ph 2403 PHARMACIST REQUIREMENTS FOR CERTIFICATION

Ph 2403.01 Pharmacist Requirements. In order to dispense hormonal contraceptives, a pharmacist shall:

- (a) Apply for, obtain, and maintain certification with the New Hampshire board of pharmacy;
- (b) Complete an ACPE and board-approved training program for hormonal contraceptives;
- (c) Have a current board-approved standing order authored and signed by a physician or an advanced practice registered nurse (APRN) that is renewed and signed on an annual basis;
- (d) Have at least \$1,000,000.00 of professional liability insurance that covers services performed under a signed and approved standing order;
- (e) Establish a separate room with 4 walls in the pharmacy that maintains security, confidentiality, and limits distraction; and
- (f) Construct, maintain, and follow written policies and procedures that establish

a course of action which the pharmacist shall follow, that includes, but is not limited to, information regarding:

- (1) Adverse reactions;
- (2) Compliance with the U.S. MEC, U.S. SPR and N.H. Standard Algorithm;
- (3) Patient confidentiality;
- (4) How to appropriately screen patients and determine when to refer to a healthcare provider; and
- (5) The process to dispense the hormonal contraceptive.

PART Ph 2404 APPLICATION AND RENEWAL

Ph 2404.01 Application.

(a) Pharmacists who seek to engage in the initiation of hormonal contraceptives therapy under this section shall file a completed "Pharmacist Initiation and Dispensing of Hormonal Contraceptives" initial application form Ph 566 revised August 2019.

(b) The initial application shall include:

- (1) A fee of \$25.00;
- (2) The verification of completion of the ACPE and board-approved training program or proof of the requisite continuing education hours within 15 days of completing the application;
- (3) A standing order signed and approved by a practitioner;
- (4) Proof of insurance which meets the standard in Ph 2403 above;
- (5) Photographic evidence of the confidential room as described in Ph 2403 above; and
- (6) Verification of policies as required by Ph 2403 above.

Ph 2404.02 Renewal Requirements.

(a) Board-approved pharmacists under this section shall renew biennially during their license renewal period.

(b) The pharmacist shall complete a renewal packet which shall include:

- (1) A completed renewal form; and

- (2) The completion of a board-approved refresher training course.

PART Ph 2405 PROCEDURES FOR PRACTICE

Ph 2405.01 Initiation and Dispensing Procedure. A pharmacist who engages in hormonal contraceptive initiation and dispensing shall:

(a) Provide each patient who seeks hormonal contraceptives with a board-approved standardized information sheet, written in plain language, regarding the hormonal contraceptive being dispensed, which includes, but is not limited to:

- (1) An indication for the use of the hormonal contraceptive;
- (2) The importance of follow up care; and
- (3) Health care referral information.

(b) Complete an initial screening with the New Hampshire Self Screening Risk Assessment Questionnaire;

(c) Complete any renewal screening deemed appropriate with the New Hampshire Self-Screening Risk Assessment Questionnaire;

(d) Ensure each patient is an appropriate candidate for receiving hormonal contraceptives, as dictated by the U.S. MEC, U.S. SPR and board-approved N.H. Standard Algorithm; and refer to a health care practitioner, if appropriate;

(e) Identify the medication being dispensed to the patient and counsel the patient regarding, but not limited to, adverse effects, follow up appointments, and the instructions for use;

(f) Provide each patient with an "After Visit" summary sheet;

(g) Based upon a patient's request, provide electronically, in writing, or fax within 24 hours to the patient's primary care practitioner, or a pharmacist referred practitioner if the patient does not have a primary care practitioner, a copy of the NH Self-Screening Questionnaire, the hormonal contraceptive that has been prescribed and dispensed to the patient, and any other relevant notes;

(h) Based upon a patient's request, provide the patient who does not have a primary care practitioner and does not wish to be referred to a primary care practitioner a written copy of their record, which includes, but not limited to, the NH Self-Screening Questionnaire; and;

(i) Counsel the patient upon receiving hormonal contraceptives regarding, but not limited to, adverse effects, follow up appointments, and review instructions of use.

Ph 2405.03 Recordkeeping Procedures. A pharmacist engaging in the initiation and dispensing of hormonal contraceptives shall, for a minimum of 7 years after a patient reaches

18 years of age, maintain documentation that includes:

- (a) The name and date of birth of the patient;
- (b) A copy of the NH Self-Screening Questionnaire completed by the patient;
- (c) Evidence that the patient was screened;
- (d) Counseling information relayed to patient;
- (e) Based upon patient request, evidence that the practitioner was provided with the self-screening questionnaire and notified of the drug dispensed;
- (f) Name, dose, strength, quantity, and directions of the hormonal contraceptive dispensed; and
- (g) Signature of the patient.

PART Ph 2406 STANDARDS OF PRACTICE

Ph 2406.01 Patient Age Requirements. Pharmacists shall only dispense hormonal contraceptives to a person who is:

- (a) At least 18 years of age, regardless of whether the person has evidence of a previous prescription from a primary care practitioner or a women’s health care practitioner for a hormonal contraceptive; or
- (b) Under 18 years of age, only if the person has evidence of a previous prescription from a primary care practitioner or women’s health care practitioner for a hormonal contraceptive.

Ph 2406.02 Pharmacist Standards of Practice.

(a) Board-approved pharmacists under this section shall comply with the most current model N.H. statewide protocol, U.S. MEC, U.S. SPR, N.H. Standard Algorithm, and any other ACPE board-approved protocols for contraceptive use.

(b) A current copy of the model N.H. statewide protocol, U.S. MEC, U.S. SPR, N.H. Standard Algorithm, and any other ACPE board-approved protocols for contraceptive use shall be kept on the pharmacy premises and be available electronically for board review upon request.

(c) Board-approved pharmacists under this section shall comply with the model N.H. statewide protocol, U.S. MEC, U.S. SPR, N.H. Standard Algorithm, and any other ACPE board-approved protocols for contraceptive use as adopted by the board and the CDC.

(d) Pharmacists shall have readily retrievable access to the American Congress of Obstetrician and Gynecologists (ACOG) guidelines for reference.

(e) Pharmacists shall maintain their verification of completion of a ACPE board- approved training or continuing education equivalent and make it readily available upon request by the board;

Ph 2406.03 Prohibited Practices and Restrictions. A pharmacist who engages in the dispensing of hormonal contraceptives shall not:

(a) Decline or refuse service to a patient who does not have a scheduled appointment for the initiation or dispensing of a hormonal contraceptive;

(b) Contract with a practitioner to gain financial compensation, or seek any financial benefit through incentive-based programs or any other inducements;

(c) Initiate, or dispense hormonal contraceptives to oneself or to their immediate family members; and

(d) Initiate, or dispense hormonal contraceptives in instances where the model N.H. statewide protocol, U.S. MEC, U.S. SPR, N.H. Standard Algorithm, and any other ACPE board-approved protocols for contraceptive use requires a referral to a practitioner.

PART Ph 2407 IMMUNITY

Ph 2407.01 Immunity. The board shall not penalize board-approved pharmacists under this chapter for following standing orders that contains a defect as long as the requirements in Ph 2400 and RSA 318:47-1 are satisfied.

Appendix

| Rule | Specific State Statute the Rule Implements |
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| Ph 2400 | RSA 318:5-a, I, V, and IX; RSA 318:47-I |