

State of Connecticut
Regulation of
Department of Consumer Protection
Concerning
Emergency and Hormonal Contraceptives

Section 1. The Regulations of Connecticut State Agencies are amended to add sections 20-XXX-1 to 20-XXX-10, inclusive, as follows:

(NEW) 20-xxx-1. Definitions

Unless otherwise expressly stated, the following terms have, for the purposes of sections 20-XXX-1 to 20-XXX-10, inclusive, of the Regulations of Connecticut State Agencies, the meanings indicated in this section:

- (1) “Care Facility” means a freestanding emergency department, as defined in section 19a-493d of the general statutes, or an emergency department located within a hospital, licensed pursuant to chapter 368v of the general statutes;
- (2) “Emergency contraceptive” has the same meaning prescribed in Public Act No. 23-52;
- (3) “Hormonal contraceptive” has the same meaning prescribed in Public Act No. 23-52;
- (4) “Patient” means an individual seeking a prescription for hormonal or emergency contraceptives from a prescribing pharmacist;
- (5) “Practitioner” means an individual, other than a prescribing pharmacist, licensed by a state, commonwealth or territory of the United States, who is authorized to issue a prescription within the scope of the individual's practice;
- (6) “Prescribing pharmacist” means a person who (i) is licensed as a pharmacist under part II of Chapter 400j of the general statutes; (ii) has completed the training requirements set forth in Section 20-xxx-2 of the Regulations of Connecticut State Agencies, (iii) has a valid training certificate evidencing completion; and (iv) is legally authorized to prescribe a hormonal contraceptive or emergency contraceptive;
- (7) “Prescription” has the same meaning as defined in Section 20-633k of the general statutes;
- (8) “Screening document for emergency contraceptive” means the document prescribed by the commissioner and posted on the department’s internet website which shall include: (1) questions to determine whether an emergency contraceptive is clinically appropriate for a patient; (2) age-appropriate health screening information; and (3) a treatment algorithm for emergency contraceptives;

(9) “Screening document for hormonal contraceptive” means the document prescribed by the commissioner and posted on the department’s internet website which shall include: (1) questions to determine whether a hormonal contraceptive is clinically appropriate for a patient; (2) age-appropriate health screening information; and (3) a treatment algorithm for hormonal contraceptives;

(10) “Treatment algorithm for emergency contraceptives” means a document, included in the screening document for emergency contraceptive, that sets forth the steps of a treatment pathway for emergency contraceptives and when a referral to a practitioner is recommended; and

(11) “Treatment algorithm for hormonal contraceptives” means a document, included in the screening document for hormonal contraceptive, that set forth the steps of a treatment pathway for hormonal contraceptives and when a referral to a practitioner is recommended.

(NEW) 20-xxx-2. Training Requirements for Prescribing of Hormonal Contraceptives and Emergency Contraceptives

(a) The department shall compile a list of educational training programs that satisfy the criteria set forth in section 3 of Public Act 23-52 and subsection (b) of this section. Such programs shall be submitted to the department in a form and manner prescribed by the commissioner. Educational training programs deemed by the department to satisfy such criteria shall be posted on the department’s internet website.

(b) Educational training programs for pharmacists and pharmacist technicians prior to prescribing hormonal contraceptives and emergency contraceptives shall be accredited by the Accreditation Council for Pharmacy Education and shall include the following topics:

- (1) The types of hormonal and emergency contraceptives that are available to patients;
- (2) Interviewing techniques for patients seeking hormonal and emergency contraceptives;
- (3) The information contained in the screening document for emergency contraceptive, the screening document for hormonal contraceptive, and how to use such documents;
- (4) The most current version of the United States Medical Eligibility Criteria for Contraceptive Use published by the Centers for Disease Control and Prevention on its internet web site, or any successor document thereto and how to use such information;
- (5) Providing patient counseling and education regarding any emergency contraceptive and hormonal contraceptive mechanism, effectiveness, benefits, risks, and instructions for use of any contraceptive selected;
- (6) Contraindications to emergency contraceptive and hormonal contraceptive use and when patient referrals to a practitioner are appropriate;
- (7) Patient assistance in the selection of an emergency contraceptive and a hormonal contraceptive;

(8) Management of side effects and when those side effects require referral to a healthcare provider or care facility;

(9) Record keeping required pursuant to 20-xxx-6; and

(10) Prohibited acts set forth in 20-xxx-10.

(c) Prior to a prescribing pharmacist and any pharmacy technician assisting in accordance with 20-xxx-3(b), a prescribing pharmacist and any assisting pharmacy technician shall successfully complete an educational training program approved by the department and shall obtain a certificate of completion from such program.

(d) Such certificate of completion shall be valid for thirty-six months from the date of completion reflected on the certificate. Upon expiration of such certificate, a pharmacist or pharmacy technician shall successfully complete a subsequent educational training program approved by the department and obtain a new certificate of completion in order to continue to prescribe hormonal and emergency contraceptives or assist with prescribing as permitted. The pharmacist and pharmacy technician shall maintain a valid certificate of completion at all times and produce a copy of such certificate of completion to the department upon request.

(NEW) 20-xxx-3. Screening

(a) Each prescribing pharmacist shall assist the patient in completing the screening document for emergency contraceptive or the screening document for hormonal contraceptive, as applicable.

(b) A pharmacy technician who has completed an educational training program approved by the department may, at the prescribing pharmacist's request, assist the prescribing pharmacist in prescribing an emergency contraceptive or hormonal contraceptive by:

(1) Providing the applicable screening document for emergency contraceptive or screening document for hormonal contraceptive to a patient and assisting a patient in completing the documents;

(2) Taking and recording the patient's blood pressure; and

(3) Documenting the patient's medical history.

(c) The completed screening document for emergency contraceptive or screening document for hormonal contraceptive, as applicable shall be reviewed by a prescribing pharmacist.

(d) Nothing in this section shall prevent a prescribing pharmacist from requesting that any screening document for hormonal contraceptive be completed more frequently than every twelve months by the patient in order to obtain a prescription for hormonal contraception.

(e) Each prescribing pharmacist shall use the screening document for emergency contraceptive and screening document for hormonal contraceptive, as applicable. Any additional information provided by the prescribing pharmacist to the patient related to the prescription of an

emergency or hormonal contraceptive shall be provided as a separate document.

(NEW) 20-xxx-4. Prescribing of Hormonal Contraception

(a) In order to prescribe hormonal contraception to a patient, a prescribing pharmacist shall:

- (1) Administer the screening document for hormonal contraceptive;
- (2) Conduct an interview of the patient; and
- (3) Confirm that the patient seeking hormonal contraception has had a visit with a practitioner within the previous three years.

(b) If a prescribing pharmacist determines that the prescribing of hormonal contraception is not clinically appropriate based on the treatment algorithm for hormonal contraceptives for any reason, such prescribing pharmacist shall refer the patient to a practitioner, the prescribing pharmacist shall not prescribe the hormonal contraceptive and document reasons on the screening documents.

(c) The prescription written by the prescribing pharmacist, including the time period for the initial filling of the prescription along with refills shall not exceed a total of twelve months.

(d) Any pharmacist may dispense a prescription written by a prescribing pharmacist or practitioner.

(e) Upon meeting with the patient, the prescribing pharmacist shall discuss and subsequently provide a copy the completed screening document for hormonal contraceptive to the patient, which shall include any reasons documented pursuant to 20-xxx-4(b), which explains the potential side effects of the hormonal contraceptive and when to seek care from a health care provider, practitioner or care facility regardless of whether the patient was prescribed a hormonal contraceptive. .

(f) The prescribing pharmacist shall ensure that they are using the most current version of the screening documents for hormonal contraceptive.

(NEW) 20-xxx-5. Prescribing of Emergency Contraception

(a) In order to prescribe emergency contraception to a patient, a prescribing pharmacist shall:

- (1) administer the screening document for emergency contraceptive; and
- (2) conduct an interview of the patient.

(b) If a prescribing pharmacist determines that the prescribing of emergency contraception is not clinically appropriate based on the screening document for emergency contraceptives for any reason, including but not limited to the treatment algorithm for emergency contraceptives for any reason, such prescribing pharmacist shall refer the patient to a practitioner, the prescribing pharmacist shall not prescribe the emergency contraceptive and document the reasons on the screening forms completed.

(c) Emergency contraception shall not have any refills.

(d) Any pharmacist may dispense a prescription written by a prescribing pharmacist or practitioner.

(e) Upon meeting with the patient, the prescribing pharmacist shall discuss and subsequently provide the completed screening document for emergency contraceptive, which shall include any reasons documented pursuant to 20-xxx-5(b), which explains the potential side effects of the emergency contraceptive and when to seek care from a healthcare provider, practitioner or care facility regardless of whether the patient was prescribed an emergency contraceptive.

(f) The prescribing pharmacist shall ensure that they are using the most current version of the screening documents for emergency contraceptive.

(NEW) 20-xxx-6. Record Keeping

(a) Completed screening documents for emergency contraceptive and completed screening documents for hormonal contraceptive shall be maintained in the same manner as the prescription on file at the pharmacy for the patient prescribed the hormonal or emergency contraceptive for at least three years.

(b) Each prescription prescribed by a prescribing pharmacist for hormonal or emergency contraceptive shall be transmitted by the prescribing pharmacist to the electronic prescription drug monitoring program established pursuant to 21a-254(j) of the general statutes within twenty-four hours of dispensation.

(c) All records created as part of any pharmacist prescribing a hormonal or emergency contraceptive shall be maintain for a minimum of three years.

(d) All records created as part of any pharmacist prescribing hormonal or emergency contraceptives shall be readily retrievable and provided to the Department, upon request, within forty-eight hours of such request.

(NEW) 20-xxx-7. Transfers

A pharmacy is not required to have a prescribing pharmacist to accept a transfer of a prescription for a hormonal contraceptive and said prescription, including a prescription written by a prescribing pharmacist may be transferred to any pharmacy.

All transferred prescriptions shall comply with the requirements set forth in section 20-616 of the general statutes.

(NEW) 20-xxx-8. Communication to a Primary Care Provider

(a) Each prescribing pharmacist that prescribes a hormonal or emergency contraceptive shall provide notice to the patient's primary care provider of the prescription within twenty-four hours of prescribing such hormonal or emergency contraceptive.

(b) In the event the patient does not disclose the identity of the patient's primary provider, the prescribing pharmacist shall provide the patient with any relevant documentation.

(NEW) 20-xxx-9. Confidentiality

(a) The prescribing pharmacist shall take reasonable precautions to ensure that the patient is able to provide the required health information, including but not limited to responses to the screening document and any interview questions, in a confidential manner.

(b) No pharmacist or pharmacy shall reveal any records or information concerning the nature of pharmaceutical services rendered to a patient in contravention of state and federal law. \

(NEW) 20-xxx-10. Prohibited Acts

(a) A prescribing pharmacist shall not prescribe any hormonal contraceptive or emergency contraceptive in an instance where the screening document for hormonal contraceptive or screening document emergency contraceptives indicates that referral to a practitioner is clinically appropriate.

(b) A prescribing pharmacist shall not prescribe any hormonal contraceptive or emergency contraceptive without a completed screening document for hormonal contraceptive or completed screening document for emergency contraceptive, as applicable.

(c) A prescribing pharmacist shall not issue a prescription for a total supply period greater than twelve-months based on the directions for use provided on the prescription.

(d) A prescribing pharmacist shall not prescribe any hormonal contraceptive or emergency contraceptive outside of the approved use stated in the product's package insert approved by the Federal Food and Drug Administration or successor agency.

(e) A prescribing pharmacist shall not prescribe a medical device, with or without hormonal contraceptives, that is implanted by a practitioner for the purpose of preventing pregnancy, including intrauterine and implantable devices.

Statement of Purpose:

To promulgate regulations pursuant to Public Act 23-52 which set forth educational training requirements and patient assessment standards for pharmacists prescribing emergency and hormonal contraceptives.