Secretary of the State File Number

6425

Regulation of the

Department of Consumer Protection

Concerning

Emergency and Hormonal Contraceptives

Regulations adopted after July 1, 2013, become effective upon posting to the Connecticut eRegulations System, or at a later date if specified within the regulation.

Posted to the Connecticut eRegulations System on December 27, 2024

EFFECTIVE DATE **December 27, 2024**

Approved by the Attorney General on **November 27, 2024**

Approved by the Legislation Regulation Review Committee on **December 17, 2024**

Electronic copy with agency head certification statement electronically submitted to and received by the Office of the Secretary of the State on

December 19, 2024

Form ICM-ECOPY (NEW 6/2015) State of Connecticut Secretary of the State



IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES

This form should be used only for regulations first noticed on and after March 23, 2015.

Electronic Copy Certification Statement

(Submitted in accordance with the provisions of section 4-172 of the Connecticut General Statutes)

Regulation of the

Department of Consumer Protection

Concerning

Emergency and Hormonal Contraceptives

Approved by the Legislative Regulation Review Committee: **December 18, 2024**eRegulations System Tracking Number: **PR2024-006**

I hereby certify that the electronic copy of the above-referenced regulation submitted herewith to the Secretary of the State is a true and accurate copy of the regulation approved in accordance with sections 4-169 and 4-170 of the *Connecticut General Statutes*.

And I further certify that in accordance with the approval of Legislative Regulation Review Committee, all required technical corrections, page substitutions and deletions, if any, have been incorporated into said regulation.

In testimony whereof, I have hereunto set my hand on **December 19, 2024**.

Julianne Avallone

Legal Director

Department of Consumer Protection

State of Connecticut

Regulation of

Department of Consumer Protection

Concerning

Emergency and Hormonal Contraceptives

Section 1. The Regulations of Connecticut State Agencies are amended by adding sections 20-633K-1 to 20-633K-10, inclusive, as follows:

(NEW) 20-633k-1. Definitions

For purposes of sections $20-633\underline{k}-1$ to 20-633k-10, inclusive, of the Regulations of Connecticut State Agencies, the following terms have the following meanings unless otherwise expressly stated:

- (1) "Care Facility" means a freestanding emergency department, as defined in section 19a-493d of the Connecticut General Statutes, or an emergency department located within a hospital, licensed pursuant to chapter 368v of the Connecticut General Statutes;
 - (2) "Commissioner" means the Commissioner of Consumer Protection;
 - (3) "Department" means the Department of Consumer Protection;
- (4) "Emergency contraceptive" has the same meaning as provided in section 20-633k of the Connecticut General Statutes;
- (5) "Hormonal contraceptive" has the same meaning as provided in section 20-633k of the Connecticut General Statutes;
- (6) "Patient" means an individual seeking a prescription for hormonal or emergency contraceptives from a prescribing pharmacist;
- (7) "Pharmacy technician" has the same meaning as provided in section 20-633k of the Connecticut General Statutes:
- (8) "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;
- (9) "Prescribing pharmacist" means a person who (A) is licensed as a pharmacist under part II of chapter 400j of the Connecticut General Statutes; (B) has completed the training requirements set forth in section 20-633k-2 of the Regulations of Connecticut State Agencies, (C) has a valid training certificate evidencing completion; and (D) is legally authorized to prescribe a hormonal contraceptive or an emergency contraceptive;

- (10) "Prescribe" has the same meaning as provided in section 20-633k of the Connecticut General Statutes;
- (11) "Screening document for an emergency contraceptive" means the document prescribed by the commissioner and posted on the department's internet website which includes: (A) questions to determine whether an emergency contraceptive is clinically appropriate for a patient; (B) age-appropriate health screening information; and (C) a treatment algorithm for emergency contraceptives;
- (12) "Screening document for a hormonal contraceptive" means the document prescribed by the commissioner and posted on the department's internet website which includes: (A) questions to determine whether a hormonal contraceptive is clinically appropriate for a patient; (B) age-appropriate health screening information; and (C) a treatment algorithm for hormonal contraceptives;
- (13) "Treatment algorithm for emergency contraceptives" means a document, included in the screening document for an emergency contraceptive, that sets forth the steps of a treatment pathway for emergency contraceptives and when a referral to a practitioner is recommended; and
- (14) "Treatment algorithm for hormonal contraceptives" means a document, included in the screening document for a hormonal contraceptive, that sets forth the steps of a treatment pathway for hormonal contraceptives and when a referral to a practitioner is recommended.

(NEW) 20-633k-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 20-633k of the Connecticut General Statutes and subsection (b) of this section. Such programs shall be submitted to the department in a form and manner prescribed by the commissioner. The department shall post on its internet website educational training programs deemed by the department to satisfy such criteria.
- (b) Educational training programs that prescribing pharmacists and pharmacist technicians are required to complete 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 use with patients seeking hormonal and emergency contraceptives;
- (3) The information contained in the screening document for an emergency contraceptive, and the screening document for a 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) The provision of 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) Guidelines for assisting patients in the selection of an emergency contraceptive and a hormonal contraceptive;
- (8) Guidelines for management of side effects and when those side effects require referral to a healthcare provider or care facility;
- (9) Record keeping required pursuant to section 20-633k-6 of the Regulations of Connecticut State Agencies; and
- (10) Prohibited acts set forth in section 20-633k-10 of the Regulations of Connecticut State Agencies.
- (c) Prior to a prescribing pharmacist and any pharmacy technician assisting a patient in accordance with section 20-633k-3(b) of the Regulations of Connecticut State Agencies, 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 recorded 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 such contraceptives as permitted pursuant to section 20-633k of the Connecticut General Statutes. 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) 20-633k-3. Screening

- (a) Except as provided in subsection (b) of this section, each prescribing pharmacist shall assist the patient in completing the screening document for an emergency contraceptive or the screening document for a hormonal contraceptive, as applicable.
- (b) A pharmacy technician who has obtained a certificate of completion from 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 an emergency contraceptive or screening document for a 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 an emergency contraceptive or screening document for a 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 a hormonal contraceptive be completed more frequently than every twelve months by the patient in order to obtain a prescription for a hormonal contraceptive.
- (e) Each prescribing pharmacist shall use the screening document for an emergency contraceptive and screening document for a 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) 20-633k-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 a hormonal contraceptive; and
- (2) Conduct an interview of the patient.
- (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 (1) refer the patient to a practitioner, (2) not prescribe the hormonal contraceptive, and (3) document the reasons for such determination and referral on the screening document for a hormonal contraceptive.
- (c) The prescription written by the prescribing pharmacist, including the time period for the initial filling of the prescription, along with any 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 of the completed screening document for a hormonal contraceptive to the patient, which shall include any documented reasons such pharmacist determined such contraceptive was not clinically appropriate pursuant to subsection (b) of this section.

(f) The prescribing pharmacist shall ensure that such pharmacist is using the most current version of the screening document for a hormonal contraceptive.

(NEW) 20-633k-5. Prescribing of Emergency Contraception

- (a) In order to prescribe an emergency contraceptive to a patient, a prescribing pharmacist shall:
 - (1) administer the screening document for an emergency contraceptive; and
 - (2) conduct an interview of the patient.
- (b) If a prescribing pharmacist determines that the prescribing of an emergency contraceptive is not clinically appropriate based on the screening document for an emergency contraceptive for any reason, including, but not limited to, the treatment algorithm for emergency contraceptives, such prescribing pharmacist shall (1) refer the patient to a practitioner, (2) not prescribe the emergency contraceptive, and (3) document the reasons for such determination and referral on the completed screening document.
 - (c) A prescription for an emergency contraceptive 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 an emergency contraceptive, which shall include any reasons documented pursuant to subsection (b) of this section, 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 such pharmacist is using the most current version of the screening document for emergency contraceptive.

(NEW) 20-633k-6. Record Keeping

- (a) Completed screening documents for an emergency contraceptive and completed screening documents for a hormonal contraceptive shall be maintained in the same manner as the prescription on file at the pharmacy that dispensed the applicable contraceptive to the patient prescribed such contraceptive not less than three years after the date of such prescription.
- (b) All records created as part of any pharmacist prescribing a hormonal or an emergency contraceptive shall be maintained for not less than three years after the date of such prescription.

(c) All records created as part of any pharmacist prescribing hormonal or emergency contraceptives shall be readily retrievable and provided to the department, upon request, by such pharmacist not later than forty-eight hours after such request.

(NEW) 20-633k-7. Transfers

- (a) A pharmacy is not required to have a prescribing pharmacist to accept a transfer of a prescription for a hormonal contraceptive and such prescription, including a prescription written by a prescribing pharmacist, may be transferred to any pharmacy.
- (b) All transferred prescriptions shall comply with the requirements set forth in section 20-616 of the Connecticut General Statutes.

(NEW) 20-633k-8. Communication to a Primary Care Provider

- (a) Except as provided in subsection (b) of this section, each prescribing pharmacist who prescribes a hormonal or an emergency contraceptive shall provide notice to the patient's primary care provider of the prescription not later than twenty-four hours after prescribing such hormonal or emergency contraceptive.
- (b) In the event the patient does not disclose the identity of the patient's primary care provider, the prescribing pharmacist shall provide the patient with any relevant documentation.

(NEW) 20-633k-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 or federal law.

(NEW) 20-633k-10. Prohibited Acts

- (a) A prescribing pharmacist shall not prescribe any hormonal contraceptive or emergency contraceptive in an instance where the screening document for a hormonal contraceptive or screening document for an emergency contraceptive 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 such contraceptive.

- (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.

Form Agency-Cert-PR-TA-ICM (Rev 11/2017) State of Connecticut Secretary of the State



IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES

This form is to be used for proposed permanent and technical amendment regulations only and must be completed in full.

AGENCY CERTIFICATION

Department of Consumer Protection

Proposed Regulation Concerning

Emergency and Hormonal Contraception
eRegulations System Tracking Number PR2024-006
I hereby certify the following:
(1) The above-referenced regulation is proposed pursuant to the following statutory authority or authorities: Public Act 2023-52 .
For technical amendment regulations proposed without a comment period, complete #2 below, then skip to #8.
(2) As permitted by Section 4-168(h) of the <i>Connecticut General Statutes</i> , the agency elected to proceed without prior notice or hearing and posted the text of the proposed technical amendment regulation on eRegulations System website on n/a .
For all other non-emergency proposed regulations, complete #3 - #7 below, then complete #8)
(3) The agency posted notice of intent with a specified comment period of not less than 30 days to the eRegulations System website on June 4, 2024 .
(4) (Complete one) \boxtimes No public hearing held or was required to be held. OR \square One or more public hearings were held on: $\mathbf{n/a}$.
(5) The agency posted notice of decision to move forward with the proposed regulation to the eRegulations System website on August 23, 2024 .
(6) (Complete one) ☐ No comments were received. OR ☐ Comments were received and the agency posted the statements specified in subdivisions (1) and (2) of CGS Section 4-168(e) to the eRegulations System website on
(7) The final wording of the proposed regulation was posted to the eRegulations System website on November 26, 2024 .
(8) Subsequent to approval for legal sufficiency by the Attorney General and approval by the Legislative Regulation Review Committee, the final regulation shall be effective
(Check <u>one</u> and complete as applicable)
igotimes When posted to the eRegulations System website by the Secretary of the State.
OR On (Date must be a <u>specific calendar date</u> not less than 11 days after submission to the Secretary of the State)
Legal Director 11/26/24 SIGNED OFFICIAL TITLE DATE (Head of Board, Agency or Commission,

or duly authorized deputy)

OFFICE OF THE ATTORNEY GENERAL REGULATION CERTIFICATION

Agency: Department of Consumer Protection

REGULATION NUMBER: PR2024-006

This Regulation is hereby APPROVED by the Attorney General as to legal sufficiency in accordance with Connecticut General Statutes § 4-169.

DATE: 11/27/2024

Signed:

Sean Kehoe

Associate Attorney General

Chief of the Division of Government Affairs

Duly Authorized

The Connecticut General Assembly

Legislative Regulation Review Committee

Senator John Kissel Senate Chair



Representative Lucy Dathan House Chair

Official Record of Committee Action

December 17, 2024

Agency: Department of Consumer Protection

Description: Emergency and Hormonal Contraceptives

LRRC Regulation Number: 2024-022A eRegulation Tracking Number: PR2024-006

The above-referenced regulation has been

Approved with Technical Corrections and Deletions

by the Legislative Regulation Review Committee in accordance with CGS Section 4-170.

Catherine M. Thomas Committee Administrator



State of Connecticut Office of the Secretary of the State

Confirmation of Electronic Submission

Re: Regulation of the Department of Consumer Protection concerning Emergency and Hormonal Contraceptives eRegulations System Tracking Number PR2024-006 Legislative Regulation Review Committee Docket Number 2024-022A

The above-referenced regulation was electronically submitted to the Office of the Secretary of the State in accordance with Connecticut General Statutes Section 4-172 on December 19, 2024.

Said regulation is assigned Secretary of the State File Number 6425.

The effective date of this regulation is December 27, 2024.

Stephanie Thomas Secretary of the State December 27, 2024

By:

/s/ Christopher R. Drake

Christopher R. Drake Director, Business Services Division