The Connecticut General Assembly

Legislative Commissioners' Office

Edwin J. Maley, Jr.

Commissioner

Leonard A. Fasano

Commissioner

Nicholas F. Bombace Director



Legislative Office Building Suite 5500 Hartford, Connecticut 06106-1591 (860) 240-8410 fax (860) 240-8414 e-mail: lco@cga.ct.gov

Memorandum

To: Legislative Regulation Review Committee

From: Legislative Commissioners' Office

Committee Meeting Date: November 26, 2024

Regulation No: 2024-22

Agency: Department of Consumer Protection

Subject Matter: Emergency and Hormonal Contraceptives

Statutory Authority: 20-633k

(copy attached)

	Yes or No
Mandatory	N
Federal Requirement	N
Permissive	Y

For the Committee's Information:

Substantive Concerns:

1. On page 1, in section 20-xxx-1(7), the agency defines "prescription" as having the meaning defined in section 20-633k of the general statutes. While the term "prescribe" is defined in the statute, the term "prescription" is not defined in section 20-633k. It is unclear if the agency meant to reference the definition for the term "prescription" in a different statute, such as section 20-635 of the general statutes.

2. On page 4, in section 20-xxx-4(a)(3), the proposed regulation requires a prescribing pharmacist to confirm that the patient seeking a hormonal contraceptive has had a visit with a practitioner within the previous three years. Section 20-633k of the general statutes contains no such requirement and authorizes such a prescription, after other conditions are met, in cases in which the patient does not provide the name of a primary care provider. In addition, legislative history shows that the intent of the legislation was to authorize such prescriptions even when a patient has been unable to access health care from a primary care provider. Section 20-633k of the general statutes authorizes the adoption of regulations only to the extent such regulations implement the provisions of the section. This provision appears to exceed statutory authority and should be removed.

Technical Corrections:

- 1. On page 1, in the introductory language, "to add" should be "by adding", for proper form.
- 2. Throughout the proposed regulation, "XXX" should be "633k", for proper form. For example, on page 1 in the introductory language, "20-XXX-1 to 20-XXX-10" should be "20-633k-1 to 20-633k-10".
- 3. On page 1, in section 20-xxx-1, the introductory language after the catchline should be rewritten as follows for proper form: "For purposes of sections 20-633k-1 to 20-633k-10, inclusive, of the Regulations of Connecticut State Agencies, the following terms have the following meanings unless otherwise expressly stated:".
- 4. On page 1, in section 20-xxx-1(6), in the fifth line, "emergency contraceptive" should be "an emergency contraceptive," for proper form.
- 5. On pages 1 and 2, in section 20-xxx-1(8) and (9), and throughout the proposed regulation, "Screening document for emergency contraceptive" and "Screening document for hormonal contraceptive", should be "Screening document for an emergency contraceptive" and "Screening document for a hormonal contraceptive", for proper form.
- 6. On pages 1 and 2, in section 20-xxx-1, the following definitions should be added and existing subdivisions redesignated for clarity: '(2) "Commissioner" means the Commissioner of Consumer Protection; (3) "Department" means the Department of Consumer Protection;' and '(7) "Pharmacy technician" has the same meaning as provided in section 20-633k of the general statutes;'.
- 7. On page 1, in section 20-xxx-1(1), "368vof the general statutes" should be "368v of the Connecticut General Statutes" and subsequent references to "the general statutes" throughout the proposed regulation should be "the Connecticut General Statutes", for proper form.
- 8. On page 1, in sections 20-xxx-1(2) and (3), "prescribed in Public Act No. 23-52" should be "as provided in section 20-633k of the Connecticut General Statutes", for proper form.

- 9. On page 1, in section 20-xxx-1(6), clause designators "(i)" to "(iv)", inclusive, should be subparagraph designators "(A)" to "(D)", inclusive, for proper form.
- 10. On pages 1 and 2, in sections 20-xxx-1(8) and (9), subdivision designators "(1)" to "(3)", inclusive, should be subparagraph designators "(A)" to "(C)", inclusive, and "shall include" should be "includes", for proper form.
- 11. On page 2, in section 20-xxx-1(11), "set forth" should be "sets forth", for proper form.
- 12. On page 2, in section 20-xxx-2(a), "3 of Public Act 23-52" should be "20-633k of the Connecticut General Statutes", for proper form, and the last sentence should be rewritten for clarity as follows: "The department shall post on its internet website educational training programs deemed by the department to satisfy such criteria."
- 13. On pages 2 and 3, in section 20-xxx-2(b), in the first line, "for pharmacists" should be "that prescribing pharmacists" and "technicians" should be "technicians are required to complete", in subdivision (2), "for patients" should be "for use with patients", in subdivision (3), "and" should be inserted after "emergency contraceptive,", in subdivision (5), "Providing" should be "The provision of", in subdivision (7), "Patient assistance" should be "Guidelines for assisting patients", and, in subdivision (8), "Management of" should be "Guidelines for management of", for clarity and consistency.
- 14. On page 3, in sections 20-xxx-2(b)(9) and (10) and subsection (c), "section" should be inserted before the regulation number and "of the Regulations of Connecticut State Agencies" should be inserted after the regulation number, for proper form.
- 15. On page 3, in section 20-xxx-2, in subsection (c), in the first line, "assisting" should be "assisting a patient", for clarity, and in subsection (d), in the fifth line, "as permitted" should be "as permitted pursuant to section 20-633k of the Connecticut General Statutes", for clarity.
- 16. On page 3, in section 20-xxx-3(a), in the first line, "Each prescribing pharmacist" should be "Except as provided in subsection (b) of this section, each prescribing pharmacist", for clarity.
- 17. On page 3, in section 20-xxx-3(c), a comma should be inserted after "applicable", for proper form.
- 18. On page 4, in section 20-xxx-4(b), in the third and fourth lines, "the prescribing pharmacist shall" should be deleted as unnecessary, "document reasons" should be "document the reasons for such determination and referral" and "screening documents" should be "screening document for a hormonal contraceptive", for consistency.
- 19. On page 4, in section 20-xxx-4(c), in the second line, a comma should be inserted after "prescription" and "refills" should be "any refills,", for proper form.

- 20. On page 4, in section 20-xxx-4(e), in the second line, "copy" should be "copy of", in the third line, "reasons documented pursuant to 20-xxx-4(b)" should be "any documented reasons such pharmacist determined such contraceptive was not clinically appropriate pursuant to subsection (b) of this section", and, in the last line, the extra period should be deleted, for proper form.
- 21. On page 4, in section 20-xxx-4(f) and on page 5, in section 20-xxx-5(f), "they are" should be "such pharmacist is", for proper form.
- 22. On page 4, in section 20-xxx-5(b), in the second line, "emergency contraceptives" should be "an emergency contraceptive", for consistency; in the third line, a comma should be inserted after "including" and after "limited to", for proper form; in the third and fourth lines, the second instance of "for any reason" should be deleted as unnecessary; in the fourth and fifth lines, "the prescribing pharmacist shall" should be deleted as unnecessary; in the fifth line, "document the reasons" should be "document the reasons for such determination and referral", for consistency; and the last line should be rewritten as "completed screening document", for clarity and consistency.
- 23. On page 5, in section 20-xxx-5(c), "Emergency contraception" should be "A prescription for an emergency contraceptive", for clarity.
- 24. On page 5, in section 20-xxx-5(e), "20-xxx-5(b)" should be "subsection (b) of this section", for proper form.
- 25. On page 5, in section 20-xxx-6(a), in the first line, "emergency contraceptive" should be "an emergency contraceptive", in the second line, "hormonal contraceptive" should be "a hormonal contraceptive" and "pharmacy" should be "pharmacy that dispensed the applicable contraceptive", and, in the third line, "prescribed the hormonal or emergency contraceptive for at least three years" should be "prescribed such contraceptive not less than three years after the date of such prescription," for clarity.
- 26. On page 5, in section 20-xxx-6(b), in the first line, "hormonal or emergency" should be "a hormonal or an emergency", in the third line, "section" should be inserted before "21a-254j" and "within" should be "not later than", and, in the fourth line, "of" should be "after", for consistency and proper form.
- 27. On page 5, in section 20-xxx-6(c), "emergency contraceptive" should be "an emergency contraceptive" and "for a minimum of three years" should be "not less than three years after the date of such prescription", for consistency and proper form.
- 28. On page 5, in section 20-xxx-6(d), in the second line, "Department" should be "department" and "upon request, within" should be "upon request, by such pharmacist not later than", and, in the third line, "of" should be "after", for proper form.
- 29. On page 5, in section 20-xxx-7, subsection designators "(a)" and "(b)" should be inserted before the two paragraphs, in newly designated subsection (a), in the second line, "said" should be "such", and, in the last line of newly designated subsection (a), a comma should be inserted after "pharmacist", for proper form.

- 30. On page 5, in section 20-xxx-8(a), in the first line, "Each prescribing pharmacist that" should be "Except as provided in subsection (b) of this section, each prescribing pharmacist who" and "emergency contraceptive" should be "an emergency contraceptive", for clarity and consistency; and in the second and third lines, "within twenty-four hours of" should be "not later than twenty-four hours after", for proper form.
- 31. On page 6, in section 20-xxx-8(b), "primary provider" should be "primary care provider", for accuracy.
- 32. On page 6, in section 20-xxx-9(a), a comma should be inserted after "including" and after "limited to", for proper form.
- 33. On page 6, in section 20-xxx-10(a), in the second line, "hormonal contraceptive" should be "a hormonal contraceptive", and, in the third line, "document emergency contraceptives" should be "document for an emergency contraceptive", for consistency.
- 34. On page 6, in section 20-xxx-10(b), in the second line, "hormonal contraceptive" should be "such contraceptive." and "or completed" and the third line of the section should be deleted, for clarity.
- 35. On page 6, in section 20-xxx-10(c), "twelve-months" should be "twelve months", for proper form.

Recommendation:

Approval in whole
with technical corrections
with deletions
with substitute pages
Disapproval in whole or in part
Rejection without prejudice

Reviewed by: Shannon McCarthy / Marie P. Grady

Date: November 26, 2024

From 2024 Supplement (Section 3 of public act 23-52)

Sec. 20-633k. Prescribing of emergency and hormonal contraceptives by licensed pharmacists. Training. Patient screening. Disclosures and notices. Assistance by pharmacy technicians. Recordkeeping. Regulations. (a) For the purposes of this section:

- (1) "Department" means the Department of Consumer Protection;
- (2) "Emergency contraceptive" means a drug, or a combination of drugs, approved by the federal Food and Drug Administration to prevent pregnancy as soon as possible following (A) unprotected sexual intercourse, or (B) a known or suspected contraceptive failure:
- (3) "Hormonal contraceptive" means a drug, including, but not limited to, a hormonal contraceptive patch, an intravaginal hormonal contraceptive or an oral hormonal contraceptive, composed of a hormone, or a combination of hormones, approved by the federal Food and Drug Administration to prevent pregnancy;
 - (4) "Legend drug" has the same meaning as provided in section 20-571;
 - (5) "Pharmacist" has the same meaning as provided in section 20-571;
 - (6) "Pharmacy" has the same meaning as provided in section 20-571;
 - (7) "Pharmacy technician" has the same meaning as provided in section 20-571; and
- (8) "Prescribe" means to order, or designate a remedy or any preparation of, a legend drug for a specific patient.
- (b) A pharmacist who satisfies the requirements established in this section, and any regulations adopted pursuant to subsection (e) of this section, may prescribe, in good faith, an emergency contraceptive or hormonal contraceptive to a patient subject to the following conditions:
- (1) The pharmacist has completed an educational training program that (A) concerns prescribing emergency contraceptives and hormonal contraceptives by a pharmacist, (B) addresses appropriate medical screening of patients, contraindications, drug interactions, treatment strategies and modifications and when to refer patients to medical providers, and (C) is accredited by the Accreditation Council for Pharmacy Education;
- (2) The pharmacist has reviewed the most current version of the United States Medical Eligibility Criteria for Contraceptive Use published by the Centers for Disease Control and Prevention, or any successor document thereto, prior to prescribing any emergency

contraceptive or hormonal contraceptive and, if the pharmacist deviates from the guidance provided in such document, documents the pharmacist's rationale in deviating from such guidance in writing;

- (3) Prior to dispensing an emergency contraceptive or hormonal contraceptive and at least once per calendar year thereafter for any returning patient, the pharmacist completes a screening document, which the department shall make available on the department's Internet web site, and the pharmacist, or the pharmacy that employs such pharmacist, retains such document for at least three years, except nothing in this subdivision shall be construed to prevent a pharmacist, in the pharmacist's professional discretion, from issuing a prescription for a hormonal contraceptive for a period not to exceed twelve months or from requiring more frequent screenings;
- (4) If the pharmacist determines that prescribing an emergency contraceptive or hormonal contraceptive to a patient is clinically appropriate, the pharmacist shall (A) counsel the patient about what the patient should monitor and when the patient should seek additional medical attention, and (B) send notice to any health care provider that the patient identifies as the patient's primary care provider or, if the patient does not disclose the identity of the patient's primary care provider, provide to the patient any relevant documentation; and
- (5) The pharmacist provides to the patient a document outlining age-appropriate health screenings that are consistent with recommendations made by the Centers for Disease Control and Prevention.
- (c) A pharmacy technician may, at a pharmacist's request, assist the pharmacist in prescribing an emergency contraceptive or hormonal contraceptive to a patient by providing screening documentation to the patient, taking and recording the patient's blood pressure and documenting the patient's medical history, provided the pharmacy technician has completed an educational training program that satisfies the requirements established in subdivision (1) of subsection (b) of this section.
- (d) Each pharmacy shall maintain copies of all documents concerning any screening performed under this section for at least three years, and each pharmacy shall, upon request by the department, make such screening documents available to the department for inspection.
- (e) The Commissioner of Consumer Protection may adopt regulations, in accordance with chapter 54, to implement the provisions of this section.