Regulation Concerning Emergency and Hormonal Contraceptives
Summary of Public Comments and DCP Response

August 23, 2024

Regulations Concerning Emergency and Hormonal Contraceptives (PR2024-006)

The Department of Consumer Protection opened a public comment period from Tuesday, June 6, 2024, through 5:00pm on Monday, July 8, 2024, to solicit public input regarding a proposed administrative regulation concerning the prescribing of emergency and hormonal contraceptives. To promulgate regulations pursuant to General Statutes §20-633k which set forth educational training requirements and patient assessment standards for pharmacists prescribing emergency and hormonal contraception.

The document attached summarizes the comments received and the Department's responses.

Very truly yours,

Julianne Avallone - Legal Director
On behalf of
Bryan Cafferelli - Commissioner
Dated: August 23, 2024

Summary of Public Comments and DCP Response

Summary of Public Comments and Responses: The Department of Consumer Protection ("Department") received and reviewed six (6) comments regarding the proposed regulation. A summary of the comments and the Department's responses are set forth below.

1. **Philip M. Hritcko** strongly supported the proposed regulation.

2. **Karl Kehrle** opposed the proposed regulation. The concern involves a statutory change that beyond the scope of the Department's authority to address in regulation.

3. **Romil Shah** expressed concerns about the circumstances in which this regulation may be enacted. This concern involves a statutory change that is beyond the scope of the Department's authority to address in regulation.

4. **Maggie Moree**, on behalf of CVS Health, provided support, but noted several suggestions to clarify the proposed language:

   Recommends removing the training certificate expiration date in Section 20-xxx-2(d) and replace with a continuing education mandate for participating pharmacists.

   Response: The statute requires specific subject matter training. A certificate of completion is necessary in order for the Department to verify such training has occurred.

   Recommends editing Section 20-xxx-4(a)(1) to provide expanded access to care by removing the requirement that an individual see a practitioner every three years.

   Response: The provision protects patients by ensuring periodic medical evaluations are performed to evaluate the suitability of the prescription, any physiological impacts on the patient and to prevent gaps in care that otherwise might occur with a prescription outside of physician's office and without access to medical records that ordinarily contain prescription information that is not required to be entered in the electronic drug prescription monitoring program (PDMP).

   Suggestion to edit Section 20-xxx-6 to prevent pharmacists from storing patient medical information in the prescription dispensing system or manual storage area, as they would a prescription.

   Response: The goal of this language is to ensure organization and accessibility of screening documents, for reference and inspection by the Department. We appreciate that certain pharmacy information systems may not be able to upload or store the screening documents. The language has been clarified to allow these records to be stored in a separate system from prescription records.

The authority to require such prescriptions be included in the PDMP is set forth in Section 21a-254(j)(2) of the general statutes. It permits the Department to designate other substances to be included in the PDMP. Inclusion allows for continuity of care and prevents gaps in care that might otherwise occur with a prescription outside of a physician's office that is not easily accessible.

5. **The Connecticut Hospital Association** (CHA) noted several suggestions related to the proposed language.

   CHA recommended deleting certain definitions because of potential conflict with existing statutes, The Department has determined the recommended deletions would result in a lack of clarity in the market. The defined terms solely pertain to the proposed regulations and do not supersede defined terms in other statutes or regulations. However, CHS did note that there was a scrivener's error where the department inserted "pharmacist technician" instead of the defined term "pharmacy technician." The Department corrected that error in the revised proposed regulation.

   In many of the comments, CHA expressed concern about reiterating certain statutory language in regulation. The Department has only done so where the statutory language is necessary to ensure context for regulatory requirements and provide operational clarity. For example, in section 20-XXX-9, the Department will not remove the language protecting patient confidentiality, as recommended by CHA, even if those protections also exist in other areas of law as this ensures an enforcement mechanism for breach specific to these proposed regulations.

   Additionally, in numerous instances CHA has not provided any data, a view or an argument regarding the proposed regulatory language. Rather, the commentor posed specific questions that ask for a legal interpretation of existing statutory language or requesting clarification of statutory language incorporated into the regulation. The Notice of Decision and public comment period is not the appropriate forum for these requests for legal opinion and it is outside of the regulatory scope of the department to address statutory language. However, the Department did note some verbiage in sections 20-XXX-4 and 20-XXX-5 should be revised to align more closely with existing statutory language. Those changes are reflected in the revised proposed regulation.

   Finally, many of the other questions posed, especially related to 20-XXX-4, are answered in the definitions section. There were a number of questions related to what the form provided by the Commissioner will look like or other specific operational questions. Since the Commissioner does not have authority to mandate forms and operationalize the regulatory framework until the regulations are codified, therefore these questions are premature.

6. **Sally Rafie**, representing the Birth Control Pharmacist, provided support but noted suggestions to clarify the proposed language related to the questionnaire and training programs, including the use of a screening document and the delineation of specific training documents.

Response: Section 20-633k of the general statutes requires the review of the CDC guidance as well as the use of screening documents. Removal of this requirement is outside the scope of the Department's regulatory authority. Specific training topics are necessary for the department to ensure consistent training across industry and evaluate the appropriateness of the training.

Proposed Amendments to Regulation

Amendment 1.

In response to commentary, the Department revised a typographical error in proposed Section 20-xxx-2(b). This change shall be made, with the amended regulation section reading as follows:

(b) Educational training programs for pharmacists and [pharmacist]pharmacy 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:

Amendment 2.

The Department has revised proposed Section 20-xxx-4(a) to comport with the enacting statutory language. This change shall be made, with the amended regulation section reading as follows

Section 20-xxx-4. Prescribing of Hormonal Contraception (a) In order to prescribe hormonal contraception to a patient, a prescribing pharmacist shall:

(1) [Administer]Ensure the screening document for hormonal contraceptive is complete;
(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.

Amendment 3.

The Department has revised proposed Section 20-xxx-5(a) to comport with statutory language. This change shall be made, with the amended regulation section reading as follows

Section 20-xxx-5. Prescribing of Emergency Contraception

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

(1) [administer]Ensure the screening document for emergency contraceptive is complete; and
(2) Conduct an interview of the patient.

Amendment 4.

In response to commentary, the Department has clarified the following subsections: Section 20-xxx-6(a) allows pharmacies to more flexibly maintain screening documents; and Section 20-xxx-6(b) clarifies the dispensing pharmacist is required to perform entry into the PDMP. Additionally, after posting the proposed regulation, the Department recognized a typographical error in proposed new Section 20-xxx-6(c). This change shall be made, with the amended regulation section reading as follows:

(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. Such records shall be organized and maintained either in hard copy at the pharmacy location or electronically in a system accessible at the pharmacy.
(b) Each prescription prescribed by a prescribing pharmacist for hormonal or emergency contraceptive shall be transmitted by the [prescribing]dispensing pharmacist to the electronic prescription drug monitoring program established pursuant to 21a-254(j) of the general statutes within twenty-four hours of such pharmacist's dispensation.
(c) All records created as part of any pharmacist prescribing a hormonal or emergency contraceptive shall be [maintain]maintained for a minimum of three years.

Amendment 5.

After posting the proposed regulation, the Department recognized a typographical error in proposed new Section 20-xxx-9(b). This change shall be made, with the amended regulation section reading as follows:

(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.[/]

The Department will make the above-cited changes to the text originally proposed and posted by the Department. The rest of the regulation language will remain as originally posted. The modified version of the regulation will be uploaded to the eRegulations system together with this document. The Department will next continue the promulgation process by forwarding these regulations to the Office of the Attorney General for review. Thank you for your interest in this proposed regulation and the work of the Department of Consumer Protection.

Very truly yours,

Julianne Avallone
Legal Director
Dated: August 23, 2024