State of Connecticut Department of Public Health

Statement of Reasons Pursuant to

Connecticut General Statutes § 4-168(e)

Comment and Response Document

April 24, 2024

Concerning

PR2022-042 Abortions

Public Comment Period: August 1, 2023 to September 1, 2023

1. Introduction

This comment response concerns the proposed regulation PR2022-042 regarding Abortions. The Commissioner of the Department of Public Health ("the Department") is proposing these revisions to sections 19-13-D54 and 19a-116-1 of the Regulations of Connecticut State Agencies to comply with Connecticut General Statutes § 19a-602 as amended by Public Act 22-19. This legislation specifies that certified nurse-midwives, advanced practice registered nurses, and physician assistants licensed in the state of Connecticut may provide abortion services including medication abortion and abortion procedures. Section 1 of the proposed regulation amends Section 19-13-D54 of the Regulations of Connecticut State Agencies to clarify definitions including the definition of medication abortion, comply with the requirements of Public Act 22-19 to include all licensed providers who may provide abortion services, and revise the subparagraphs on reporting and standards of care to reflect best practices. Section 1 also incorporates and updates those provisions regarding informed consent, counseling, and emergency preparedness previously located in Section 19a-116-1 of the Regulations of Connecticut State Agencies that are statutorily required pursuant to section 19a-116-1 of the Regulations of Connecticut State Agencies to avoid duplication.

The Department received six public comments in writing regarding this proposed regulation.

2. Rule-making Process

On February 21, 2023, the Department posted a Notice of Intent to adopt the proposed regulation pursuant to Connecticut General Statutes § 4-168(a). On March 30, 2023, the Department implemented policies and procedures as authorized by Conn. Gen. Stat. § 19a-483c(b). Policies and procedures shall remain in effect until final regulations are adopted. No request for a public hearing was made.

The public comment period was conducted from August 1, 2023 to September 1, 2023. A total of six written public comments were submitted to the Department via the eRegulations system or via email.

In accordance with Connecticut General Statutes § 4-168(e), this report includes:

- (1) Principal reasons in support of or in opposition to the proposed regulations, and the Department's reasons for accepting or rejecting such considerations; and
- (2) The final wording of the proposed regulation.

3. Comments and Responses

Summary of response: The Department notes that the initial revisions to these proposed regulations were made to ensure conformity with the provisions of Public Act 22-19, amending Conn. Gen. Stat. § 19a-602, and specifying that certified nurse-midwives, advanced practice registered nurses, and physician assistants licensed in the state of Connecticut may provide abortion services within the scope of their education, training and practice. At the commissioner's discretion, the Department will respond to public comment by further amending the proposed regulation, while continuing to meet the statutory

requirements of Conn. Gen. Stat. § 19a-116. The responses below address the content of all comments received in writing during the public comment period, consolidated by topic.

(A) Comments related to applicability

(1) **Comment:** One commenter sought clarity on whether proposed Sec. 19a-116-1 applies to hospitals or to clinics operated under a hospital's license.

Response: The statutory definition of outpatient clinic explicitly excludes hospitals. Conn. Gen. Stat. § 19a-490(m) defines outpatient clinic as "an organization operated by a municipality or a corporation, other than a hospital" (emphasis added).

(2) **Comment:** Medical providers commented that a full review and repeal of any and all aspects of state regulation that are medically unnecessary, and may additionally be counter to patient health and safety, is warranted. These commenters noted the Connecticut state policy interest in expanding and securing reproductive freedom in keeping with sister states. These sister states have recently shifted abortion regulation into overall healthcare regulation, rather than singling abortion services out for additional regulation, in order to recognize the safety of abortion care as part of normal healthcare services.

Response: The Department is statutorily required to regulate abortion pursuant to Conn. Gen. Stat. § 19a-116.

(B) Comments related to reporting requirements

(1) **Comment:** Commenters sought clarification regarding reporting obligations for medication abortions, as defined in the proposed regulation, that occur outside of a healthcare setting.

Response: The federal Food and Drug Administration protocol for medication abortion links the regulation of medication abortion to the setting and location of the *prescription* of the medication, regardless of the location of the abortion. The Department would like to clarify that medication abortion is covered by these regulations only to the extent that they are prescribed, or services related thereto are provided, by providers at an outpatient clinic as defined by Conn. Gen. Stat. § 19a-490(m). The Department has added a definition of abortion services to the proposed regulation, based on the language of Conn. Gen. Stat. § 19a-116, to clarify the scope of the regulation as encompassing both medication abortion and abortion procedures.

(2) **Comment**: One commenter requested clarification regarding the proposed removal of language in Sec. 19-13-D54(c) specifying that data reported on abortions will be used *"only for statistical purposes."*

Response: No patient or provider identifying data will be required as part of the reporting requirements under Sec. 19-13-D54(c) as revised. The Department has revised the reporting requirements in the proposed amended regulation to meet those minimum data points to support US Centers for Disease Control and Prevention (CDC) purposes.

(3) Comment: Commenters proposed removing all reporting requirements, or alternatively suggested lengthening the reporting timeframe from the current seven days to annual or monthly at most in keeping with other states. These comments also opposed reporting requirements containing the state of residence of patients, proposing alternatively to indicate only whether the patient is a resident or from out of state if reporting requirements are retained at all. Related comments requested narrowing the reporting requirement explicitly to only those abortions physically occurring in a licensed healthcare facility, and excluding medication abortion entirely.

Response: The Department will revise the proposed amended regulation to streamline the reporting requirements to meet those minimum data points to support CDC purposes. The Department will amend the proposed regulation to require reporting on an annual basis. See response to comment (1) above regarding the application of the reporting requirements to medication abortion.

(4) **Comment**: Several commenters raised concerns about patient confidentiality in the reporting requirements.

Response: The Department will revise the proposed revision to streamline the reporting requirements to meet those minimum data points to support CDC purposes. No patient or provider identifying data is required to be reported.

(5) **Comment:** One commenter raised concerns about the removal of the prior 2 year record retention schedule in Sec. 19-13-D54(c), and expressed concern and confusion about a potential extension of the record retention requirements for abortion reporting.

Response: The Department will revise the proposed revision to streamline the reporting requirements to meet those minimum data points to support CDC purposes. The record retention schedule as set by the Department in the State Records Management Program Policies remains unchanged at 2 years from receipt date.

(C) Comments related to standards of care

(1) **Comment:** The Department received comments requesting the removal of a list of requirements in Sec. 19-13-D54(h) and Sec. 19a-116-1(c) to modernize the language and remove the singling out of abortion as compared to other healthcare services which are not separately regulated by the state. Commenters noted that the aspects of care listed in Sec. 19-13-D54(h) repeat standards of care already required by law for all medical care, or present potential barriers to best practices in abortion-related care that are not evidence-informed. Specific comments cited current best practices and clinical standards of care in reproductive healthcare professions as evidence for why the list of requirements in Sec. 19-13-D54(h) is unnecessary or burdensome and does not serve the public health. Alternative recommendations were made in comments to clarify and strengthen provider discretion in following the list enumerated in Sec. 19-13-D54(h).

Response: The Department agrees that best practices and clinical standards of care are in place without reiterating or singling them out in regulation. The Department will revise the proposed revision to eliminate the list of requirements in Sec. 19-13-D54(h) and Sec. 19a-116-1(c) as permitted by statutory requirements under Conn. Gen. Stat. § 19a-116.

(2) Comment: The Department received a comment regarding the provision of abortion care by physician assistants, requesting removal of proposed language in Sec. 19-13-D54(b) specifying that non-physician providers "may only perform medication and abortion procedures under and in accordance with said chapters" referring to the licensing statutes for physician assistants, certified nurse-midwives, and advanced practice registered nurses. This comment stated that physician assistants already are required by their practice act to perform only those procedures that are within their education and clinical training, and thus (b) is duplicative.

Response: The Department agrees that health care providers authorized by statute to provide abortion services pursuant to Conn. Gen. Stat. § 19a-602, and licensed pursuant to their practice statutes, are bound to provide care within their education, training, and scope of practice and under their practice statutes.

Comment: Commenters questioned the utility of requiring distinct standards of quality assurance and risk management in healthcare facilities where abortions may take place, as these facilities will have policies in place for quality assurance and risk management for all the healthcare services they provide.

Response: The Department notes that the statutory provision for regulations governing abortions under Conn. Gen. Stat. § 19a-116 do not mandate regulation of quality assurance or risk management. This provision will be removed.

(D) Comments related to right to religious freedom

(1) **Comment:** Commenters opposed the retention of the religious objection provision in Sec. 19-13-D54(g), questioning the statutory basis for the provision, and arguing that the First Amendment to the Constitution and Connecticut law already protect freedom of religion such that subsection (g) as phrased is overbroad. Commenters suggest removing (g), or in the alternative suggest narrowing the refusal provision to retain language only regarding "sincerely held religious beliefs."

Response: The Department agrees that the right to freedom of religion is protected elsewhere in state and federal law, and abortion services do not need to be singled out in regulation. The Department will revise the proposed revision to eliminate the religious objection provision in Sec. 19-13-D54, and notes that such provision is not mandated by Conn. Gen. Stat. § 19a-116.

(E) Comments related to informed consent

(1) **Comment:** Commenters opposed the requirement that any informed consent received via an interpreter require signature in Sec. 19a-116-1(d), questioning the statutory authority for requiring such signature before the abortion can proceed.

Response: The Department agrees that the statutory mandate for regulation under Conn. Gen. Stat. § 19a-116 does not include a signature requirement on informed consent offered via an interpreter. This provision will be removed.

(F) Comments related to counseling requirements

- (1) **Comment:** Commenters oppose the retention of counseling provisions that place requirements only on abortion services and not on other types of healthcare. Specific comments oppose Sec. 19-13-D54(e)(10) requiring post-abortion counseling to include family planning as hostile to accessing abortion care by suggesting that existing standards of care are insufficient to meet the needs of patients before, during or after seeking abortion care.
 - **Response**: Conn. Gen. Stat. § 19a-116(4) requires the Department to adopt regulations that set standards for counseling, and specifically requires regulatory standards regarding family planning after receiving abortion services. The Department recognizes that counseling in abortion services should not be singled out, and will revise the proposed regulations to balance statutory requirements while deferring to existing standards of care and best practices.
- (2) **Comment**: Commenters oppose the addition of Sec. 19a-116-1(f) on the grounds that it exceeds the scope of Conn. Gen. Stat. § 19a-601 because it adds a requirement to counsel adult patients, not just minors who are covered explicitly under Conn. Gen. Stat. § 19a-601, permitting only those counselors as defined in Conn. Gen. Stat. § 19a-600(1).

Response: Conn. Gen. Stat. § 19a-116(4) requires the Department to adopt regulations that set standards for counseling for all patients, and Conn. Gen. Stat. § 19a-601 adds specific requirements for minors.

(G) Other comments

(1) **Comment:** Several commenters requested a full repeal of the entirety of the regulations pertaining to abortion within the Public Health Code, on the grounds that current evidence-based best practices demonstrate that such regulations impede patient-centered care and single out abortion services for onerous requirements without medical justification rather than treating abortion care as part of healthcare.

Response: The Department is statutorily required to regulate abortion according to Conn. Gen. Stat. § 19a-116.

4. Final wording of the proposed regulation:

Connecticut Department of Public Health Regulation Concerning **Abortions**

Section 1. Section 19-13-D54 of the Regulations of Connecticut State Agencies is amended as follows:

Sec. 19-13-D54. Abortions

- [(a) No abortion shall be performed at any stage of pregnancy except by a person licensed to practice medicine and surgery in the State of Connecticut.]
- (a) Definitions. As used in this section:
- (1) "Abortion" means the induced termination of a pregnancy for purposes other than producing a live birth. Methods of abortion include but are not limited to medication abortions and abortion procedures;
- (2) "Abortion services" means the provision of care related to induced abortion, including but not limited to medication abortion and abortion procedures, provided by health care providers as defined in this section and authorized pursuant to Section 19a-602 of the Connecticut General Statutes;
- (3) "Commissioner" means the Commissioner of the Department of Public Health or the Commissioner's designee;
- (4) "Health care provider" means a physician licensed pursuant to chapter 370 of the General Statutes, advanced practice registered nurse licensed pursuant to chapter 378 of the General Statutes, a nurse-midwife licensed pursuant to chapter 377 of the General Statutes and a physician assistant licensed pursuant to chapter 370 of the General Statutes; and
- (5) "Medication abortion" means the induced termination of a pregnancy using pharmacological agents.
- (6) "Outpatient clinic" has the same meaning as provided in Section 19a-490 of the Connecticut General Statutes.
- (b) A physician licensed pursuant to chapter 370 of the General Statutes, an advanced practice registered nurse licensed pursuant to chapter 378 of the General Statutes, a nurse-midwife licensed pursuant to chapter 377 of the General Statutes, and a physician assistant licensed pursuant to chapter 370 of the General Statutes, may provide abortion services under and in accordance with said chapters.
- [[(b)] (c) All [induced] abortions [will] shall be reported to the commissioner [within seven days] annually by the [physician] health care provider [performing the procedure] providing the abortion

services [to the commissioner of public health who will maintain such reports in a confidential file and use them only for statistical purposes except in cases involving licensure]. Such reports [will] shall specify the date of abortion services provided, [place where performed] the licensure type of the health care provider who provided the abortion services, [age of woman and town and state of residence] the age of the patient, whether the patient is a Connecticut resident or a resident of another state, [approximate duration of pregnancy] and method of abortion [and explanation of any complications]. The name of the [woman] patient will not be reported. These records will be destroyed [within two years after date of receipt] in accord with applicable record retention law and schedules. [In addition, a fetal death certificate shall be filed for each fetus born dead which is the result of gestation of not less than twenty weeks, or a live birth certificate shall be filed for each fetus born alive regardless of gestational age, as provided in sections 7-48 and 7-60 of the Connecticut General Statutes. If a live born fetus subsequently dies, a death certificate shall be filed as provided in section 7-62b of the Connecticut General Statutes.]

- [(c) All induced abortions after the second trimester as verified by ultrasound, last menstrual period and pelvic exam, shall be done only in a licensed hospital with a department of obstetrics and gynecology and a department of anesthesiology.]
- (d) Abortions performed after the second trimester shall be performed only in a licensed hospital or licensed ambulatory surgery center.
- [(d)] (e) All outpatient clinics [operated by corporations or municipalities] where [abortions] abortion services are [performed] provided shall [develop] implement standards to control and ensure the quality of [medical] care provided to patients having abortions. These standards shall [include] be consistent with the applicable nationally recognized clinical standards of care. These standards shall include the following, as applicable:[but not necessarily be limited to:]
- (1) [verification] <u>Verification</u> of pregnancy and determination of duration of pregnancy;
- (2) [pre-operative] Pre-abortion service instruction and counseling:
- (3) [treatment] Abortion service permission and informed consent; and
- [(4) pre-operative history and physical examination;]
- [(5) pre-operative laboratory testing for blood Rh factor;]
- [(6) prevention of Rh sensitization;]
- [(7) examination of the tissue by a pathologist;]
- [(8) receiving and recovery room facilities;]
- [(9) a standard operating rooms;]
- [(10)] (4) [post-operative] Post-abortion services counseling including family planning.[; and
- (11) a permanent record.]
- [(e) There shall be a mechanism for continuing review to evaluate the quality of records and the quality of clinical care. This review shall include all deaths, complications, infections and such other cases as shall be determined by the chief of the department of obstetrics and gynecology of the hospital clinic medical director.
- (f) No person shall be required to participate in any phase of an abortion that violates the provider's judgment, philosophical, moral or religious beliefs.
- (g) If the newborn shows signs of life following an abortion, those appropriate measures used support life in a premature infant shall be employed.]

- (f) Informed consent. Prior to providing abortion services, the patient's health care provider shall obtain informed consent from the patient, in a manner consistent with the standards of practice of the health care provider's profession.
- (g) Counseling. Counseling shall be provided to all patients, and counseling may be provided by the health care provider or a person who meets the definition of counselor in section 19a-600 of the General Statutes. For minor patients, as defined in section 19a-600 of the General Statutes, the outpatient clinic shall comply with the requirements of section 19a-601 of the General Statutes.
- (h) Emergency preparedness. Each clinic shall formulate and implement when necessary a plan for the safety of the patients in the event of fire, natural and other disasters, and bomb threat.
 - (1) Fire. A written plan shall include but not necessarily be limited to:
 - (A) <u>Posted fire evacuation plans in prominent areas showing two evacuation</u> routes;
 - (B) Fire drills conducted at unexpected times, at least quarterly on each shift;
 - (C) A written record of each fire drill including date, time, personnel in attendance and evaluation;
 - (D) <u>Tasks and responsibilities assigned to all personnel; and,</u>
 - (E) An annual review and acceptance of the plan by the local fire marshal.
 - (2) <u>Natural and other disasters. A written plan shall include but not necessarily be</u> limited to:
 - (A) Policies for internal and external disasters;
 - (B) Notification of designated persons;
 - (C) Orderly patient removal and relocation if required;
 - (D) Accountability of patients and staff during evacuation; and
 - (E) Patient notification in the event of an interruption in services.
 - (3) Bomb threat. A written plan shall include but not necessarily be limited to:
 - (A) Collection of all information from the caller by the recipient of the call;
 - (B) Notification of emergency and administrative personnel;
 - (C) <u>Total communication and coordination between emergency and facility personnel;</u>
 - (D) Responsibilities of all staff during bomb threat;
 - (E) Orderly patient removal and relocation if required; and
 - (F) Accountability of patients and staff during evacuation.

Sec. 2. Section 19a-116-1 of the Regulations of Connecticut State Agencies is repealed.