

Pursuant to the authority vested in the Commissioner of Health by Public Health Law section 2803, Section 756.3 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended and Section 756.4 is repealed and replaced, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 756.3 is amended to read as follows:

The operator shall ensure that:

- (a) prior to [performing] the [procedure] abortion service, the patient receives a [complete physical examination] clinically relevant examination, which may be satisfied, when clinically appropriate, through a review of the patient's medical history and discussion of patient symptoms conducted through telemedicine. [with appropriate tests for a positive pregnancy diagnosis and sonography if there is a question of gestational age, and] T[t]he results [are] of such examination shall be documented in the patient's medical record;
- (b) after [the] a procedure, an evaluation of the [physical and emotional] status of the patient is made and documented in the patient's medical record;
- (c) information and counseling about [alternative] methods of [birth control] contraception are made available [by a health care professional] to all patients who want such information;
- (d) referral is made to another facility for family planning services, if not available at the center, and if desired by the patient; and
- (e) [the determination of blood group and Rh type is made prior to the termination of pregnancy. The patient is evaluated for the risk of sensitization to Rho(D) antigen and,] a determination of blood group and Rh type, if clinically indicated, is made in accordance

with evidence based clinical guidelines. [i]If the use of Rh immune globulin is indicated and the patient consents, an appropriate dosage is administered within 72 hours after the termination of pregnancy.

Section 756.4 is REPEALED and a new section 756.4 is added to read as follows:

756.4 Health care practitioner services

The operator shall ensure that:

- (a) a health care practitioner licensed, certified, or authorized under title eight of the education law, acting within such practitioner's lawful scope of practice, performs the abortion; and
- (b) an abortion is performed only when, according to the practitioner's reasonable and good faith professional judgment based on the facts of the patient's case, the patient is within twenty-four weeks from the commencement of pregnancy, or there is an absence of fetal viability, or the abortion is necessary to protect the patient's life or health.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

The statutory authority is provided under Public Health Law (PHL) § 2803(2), which permits the Public Health and Health Planning Council (PHHPC), upon approval of the Commissioner of Health, to adopt rules necessary to effectuate the provisions and purposes of PHL Article 28.

### **Legislative Objectives:**

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost. Specifically, PHL § 2800 provides that “Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.”

## **Needs and Benefits:**

The proposed regulatory changes are necessary to protect and promote the health of New Yorkers seeking to access abortion services, consistent with PHL § 2800. The proposed amendments will better enable abortion service clinics, as PHL Article 28 diagnostic and treatment centers, to provide safe, high-quality services by aligning the regulations with current clinical standards for providing abortion care. In particular, repeal of section 756.4, which limited provision of abortion care to physicians, and replacement with language that mirrors PHL § 2599-bb, is necessary in light of the passage of the Reproductive Health Act of 2019. Specifically, the Act affirmed that any health care provider—not merely physicians—licensed and certified under Title 8 of the Education Law and acting within their scope of practice may provide abortion care. The proposed regulatory changes will thus advance the purposes of the Reproductive Health Act, which aimed to codify into state law the fundamental protections relating to abortion access articulated in *Roe v. Wade* and ensure access to safe, legal abortion in New York State.

The proposed regulatory amendments are also necessary to conform New York’s abortion regulations to recent federal case law relating to abortion access, including *Whole Women’s Health v Hellerstedt* (579 U.S. \_\_\_, 136 S.Ct. 2292 [2016]), *June Medical Services LLC v Russo* (591 U.S. \_\_\_, Nos. 18-1323, 18-1460, [2020]), and *Am. Coll. of Obstetricians & Gynecologists v United States FDA* (2020 US Dist LEXIS 122017 [D Md July 13, 2020]). Specifically, section 756.4(b), which requires a physician with admitting privileges at a hospital to conduct an abortion, is unconstitutional according to a recent United States Supreme Court case in *June Medical Services*, which held that a similar Louisiana law requiring physician hospital admitting privileges in order to conduct an abortion poses an undue burden on a woman’s right to abortion and is therefore unconstitutional.

With respect to the proposed amendments to section 756.3(a), which would permit clinically-relevant examinations to be conducted via telemedicine, this change is required for consistency with a recent ruling from the United States District Court for the District of Maryland. In that case, the court granted a nationwide preliminary injunction requiring that the U.S. Food and Drug Administration (FDA) temporarily suspend enforcement of the in-person dispensing requirements for the medication mifepristone, when used for medication abortion (*Am. Coll. of Obstetricians & Gynecologists v United States FDA*, 2020 US Dist LEXIS 122017, at \*1 [D Md July 13, 2020]). The Court held that the FDA's requirement that mifepristone be dispensed in person during the COVID-19 emergency improperly infringed on access to constitutionally protected medication abortions.

Similarly, subdivisions (a) and (e) of section 756.3 unnecessarily subject all patients, regardless of clinical necessity, to COVID-19 risks by requiring in-person physical examinations and Rh factor testing in order to access abortion during the pandemic. Although the COVID-19 state of emergency will eventually resolve, subdivisions (a) and (e) of section 756.3 must be amended as proposed to ensure that current regulatory requirements do not create barriers to accessing abortion services when in-person visits are not clinically necessary.

## **COSTS:**

### **Costs to Private Regulated Parties:**

The private parties subject to the proposed regulations are licensed diagnostic and treatment centers (D&TCs). This proposal is expected to have minimal costs on D&TCs, because the amendments will bring the regulations in line with current clinical practices.

**Costs to Local Government:**

This proposal will not impact local governments.

**Costs to the Department of Health:**

The Department will utilize existing resources to review compliance with the amended regulatory requirements.

**Costs to Other State Agencies:**

The proposed regulatory changes will not result in any additional costs to other state agencies.

**Local Government Mandate:**

No new local government program, project or activity is required by the proposed regulations.

**Paperwork:**

No new paperwork requirements would be imposed under the proposed regulatory changes.

**Duplication:**

These regulatory amendments do not duplicate existing State or federal requirements.

**Alternatives:**

The Department found no viable alternatives to the proposed regulations. Not amending the regulations was rejected as an option, because the existing regulations, adopted over 30 years ago, are not aligned with current clinical best practices. Failing to make the proposed regulatory changes would also place New York State at odds with federal law, to the extent that current regulations require that at least one physician in the clinic has admitting privileges at a hospital; similar admitting privileges requirements were found unconstitutional by the U.S. Supreme Court in 2016 and 2020 (*see Whole Women's Health v Hellerstedt*, 136 S.Ct. at 2292; *June Medical Services*, Nos. 18-1323, 18-1460).

**Federal Standards:**

The proposed regulations do not duplicate or conflict with any federal regulations. Indeed, this proposal will bring the Department's regulations in line with federal case law, including two recent U.S. Supreme Court decisions: *Whole Women's Health v Hellerstedt* (136 S.Ct. at 2292) and *June Medical Services* (Nos. 18-1323, 18-1460).

**Compliance Schedule:**

The regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

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**STATEMENT IN LIEU OF  
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.



**STATEMENT IN LIEU OF  
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

**STATEMENT IN LIEU OF  
JOB IMPACT STATEMENT**

A Job Impact Statement for the proposed regulatory amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

## ASSESSMENT OF PUBLIC COMMENT

Fifteen (15) public comments were received from various stakeholders including but not limited to reproductive rights advocates, health care providers, civil rights advocates, individuals, and members of the New York State Assembly.

The comments and the Department's responses are summarized below.

Note: Of the 15 comments received, 13 contained the same content in support of these regulatory changes. The content of those comments are summarized in the first two comments below.

**COMMENT:** Numerous comments were received in support of the regulatory changes, highlighting the positive impact these updates will have in removing barriers to abortion access. Commenters noted that the proposed regulatory updates will better reflect current clinical standards of care, remove any unnecessary barriers that may impede access to abortion services, and better support provision of abortion through telehealth.

**RESPONSE:** These comments in support are noted by the Department. No change was made to the regulation in response to these comments.

**COMMENT:** Numerous comments were also received in support of removing the assessment of a person's emotional status following an abortion. Commenters praised that this change helps to eliminate abortion stigma from New York's Public Health Law.

**RESPONSE:** These comments in support are noted by the Department. No change was made to the regulation in response to these comments.

**COMMENT:** One commenter recommended that the Department repeal Section 756.3 in totality. This commenter stated that specific regulations for medical care that are clinically comparable to abortion do not exist and by keeping this language in regulation the Department is perpetuating the notion that the law regards abortion as a disfavored process.

**RESPONSE:** The Department views this regulation as an important affirmation of the rights of individuals to obtain abortion care in New York State. This regulation sets a minimum standard of care for abortion services which aligns with other nationally recognized standards of care developed by academic and professional service organizations. These standards are not meant to be punitive or restrictive in any way, but to ensure any individual obtaining an abortion in New York State is afforded quality care.

**COMMENT:** One commenter recommended that as part of this regulatory update and amendment, the Department should also update language in section 755.3(b)-(d) which outlines requirements related to the distribution of blood and blood products. This commenter suggests that the Department should expand the list of providers allowed to provide blood and blood products.

**RESPONSE:** This comment is outside of the scope of proposed regulatory changes. No changes were made as a result of this comment.

**COMMENT:** Comments were received that focused on the use of the term “abortion procedure” in the updated regulatory language. Commenters suggested minor updates to the proposed regulatory language in section 756.3 including replacing the phrase, “prior to performing the procedure” with “prior to the abortion service” and striking and replacing “the” with “a” when referring to abortion services.

**RESPONSE:** The Department appreciates this feedback and agreed that language used in this regulation should be affirming in tone and impact. In response to these comments the Department has made insubstantial amendments to section 756.3 to more accurately reflect the purpose and intent of the regulation.