Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 201, 206 and 225 of the Public Health Law, Part 12 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 12.13 is REPEALED.

Section 12.20 is REPEALED.

A new section 12.21 is added, under the new title "REPRODUCTIVE HEALTHCARE STANDARDS," to read as follows:

Section 12.21. Determination of blood group and Rh type and administration of Rh immune globulin.

(a) It shall be the duty of the physician, licensed midwife or nurse practitioner attending a pregnant person to take or cause to be taken a sample of their blood to determine blood group and Rh type in accordance with evidence based clinical guidelines.

(b) It shall further be the duty of the attending physician, licensed midwife or nurse practitioner to evaluate every such patient for the risk of sensitization to Rho (D) antigen in accordance with evidence based clinical guidelines and if the use of Rh immune globulin is indicated, and the patient consents, to cause an appropriate dosage thereof to be administered as clinically indicated.

Pursuant to the authority vested in the Commissioner of Health by sections 363-a(2) and 365-a(2) of the Social Services Law, subdivision (e) of section 505.2 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

505.2 Physicians' services.

* * *

(e) Abortion.

(1) Definition. [An abortional act is the procedure or procedures by which an abortion is induced and completed; this being either medical, surgical or both, the words abortional act refer to either or both.] <u>For purposes of this section, an abortion shall include medication and procedural abortion that both a pregnant person and provider agree are needed.</u>

[(2) Where care may be provided. An abortional act shall be performed subject to the requisites set forth in 10 NYCRR 12.20.]

[(3)]<u>(2)</u> Who may provide service. [(i)] <u>Abortion may be performed by a health care practitioner licensed, certified, or authorized under title eight of the Education Law, acting within their lawful scope of practice.</u> [An abortional act is an obstetrical procedure and shall be performed only by a physician with a currently valid license to practice medicine and surgery in the State of New York and in accordance with the medical staff rules of the hospital or qualifying facility where the abortional act is performed.

(ii) No physician or other person shall be required to perform or participate in a medical procedure which may result in the termination of a pregnancy.]

[(4)] (3) Establishment of diagnosis of pregnancy. Prior to the performance of an abortion[al act], the health care practitioner must determine and document the estimated duration of the pregnancy in accordance with evidence based clinical guidelines and section 2599-bb of the Public Health Law. [positive evidence of pregnancy by test result, history and physical examination or other reliable means shall be recorded on the patient's medical chart, with an estimate of the duration of the pregnancy.]

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the proposed revisions is set forth in Public Health Law (PHL) sections 201, 206 and 225, as well as Social Services Law (SSL) sections 363-a(2) and 365-a(2). Section 201(1)(l) of the PHL establishes the powers and duties of the New York State Department of Health (Department), which include promoting diagnostic and therapeutic services for maternal health, as well as acting as the single state agency for the provision of the medical assistance program, also known as Medicaid. Section 206 of the PHL requires the Commissioner of Health to establish rules and regulations for the determination of asymptomatic conditions including Rh sensitivity, and establishes the Commissioner's authority to enforce the PHL, the State Sanitary Code and the requirements of the medical assistance program. Section 225 of the PHL sets forth the powers and duties of the Public Health and Health Planning Council (PHHPC), which include the authority to establish, amend and repeal the regulations known as the State Sanitary Code, subject to the approval of the Commissioner of Health. Further, section 225(5)(a) of the PHL allows the State Sanitary Code to address any matter affecting the security of life or health, or the preservation or improvement of public health, in New York State.

Additionally, SSL section 363-a(2) establishes the Department's authority to promulgate regulations needed to implement the medical assistance program, and SSL section 365-a(2) requires the Department to determine the scope of standard coverage under the medical assistance program.

Legislative Objective:

The legislative objective of sections 201, 206 and 225 of the PHL are to ensure that the Department of Health, through the Commissioner of Health and PHHPC, protect public health by adopting regulations in the State Sanitary Code (SSC) that effectively promote diagnostic and therapeutic services for maternal health and establish rules for the determination of asymptomatic conditions such as Rh sensitivity. In accordance with that objective, this regulation amends the SSC by revising Title 10 of New York Codes, Rules and Regulations (NYCRR) Part 12 to accord with provisions of the Reproductive Health Act of 2019.

Additionally, SSL section 363-a(2) establishes the Department's authority to promulgate regulations needed to implement the medical assistance program, and SSL section 365-a(2) requires the Department to determine the scope of standard coverage under the medical assistance program.

Needs and Benefits:

Neither Part 12 of Title 10 nor Part 505 of Title 18 has been modified since the passage of the Reproductive Health Act of 2019, and the provisions subject to amendment in this proposal derived their authority from PHL, section 4164, which was repealed by the Reproductive Health Act. Consequently, the proposed amendments are necessary to reconcile the regulations with the statute in its current form.

The Reproductive Health Act added a new Article 25-A to the PHL that expanded the types of otherwise qualified health care practitioners who may perform abortions, enshrined a fundamental right to carry a pregnancy to term, give birth to a child, or have an abortion, and explicitly stated that it was "the intent of the legislature to prevent the enforcement of laws or regulations that are not in furtherance of a legitimate state interest in protecting a woman's health

that burden abortion access." As such, it is necessary to repeal section 12.20 of Title 10 and the corresponding provisions of subdivision 505.2(e) of Title 18.

What is now compartmentalized as section 12.13 of Title 10 contains two provisions applicable to abortion care that are inconsistent with both current standards of clinical care and recent changes to the abortion provisions in regulations authorized by Article 28 of the PHL. Moreover, it is both legally inaccurate and medically inappropriate that regulations governing abortion care be organized under a heading entitled "Protection of Infants and Children Against Hazards," when in fact these provisions are meant to protect the health and lives of people of childbearing age. For that reason, the proposal will create a new subject heading under Part 12 entitled "Reproductive Healthcare Standards," to clarify the regulation's relevance and better facilitate public access to its contents.

Additionally, the rulemaking will amend subdivision of 505.2(e) of Title 18 to modernize the definition of abortion to expressly include medication and procedural services as deemed appropriate by patient and physician; to clarify that abortion services may be provided by any healthcare practitioner licensed in New York State and acting within their lawful scope of practice; and to clarify that said practitioners should determine a patient's estimated duration of pregnancy in accordance with the requirements of PHL section 2599-bb and evidence-based clinical guidelines.

COSTS:

Costs to Private Regulated Parties:

There are no anticipated costs to regulated parties, including physicians, licensed midwifes and nurse practitioners attending a pregnant person, because the current regulations already require these individuals to take or cause to be taken a sample of blood to determine blood group and Rh type. In addition, the changes to Title 18 modernize and clarify the

definition of abortion but make no actual changes to current provision of services or scope of practice. Therefore, there are no anticipated costs to regulated parties.

Cost to Local Government:

There are no anticipated costs to local governments associated with this regulation.

Cost to the Department of Health:

There are no anticipated costs to the Department of Health associated with this regulation.

Cost to Other State Agencies:

There are no anticipated costs to other state agencies associated with this regulation.

Local Government Mandates:

This regulation imposes no new government mandates.

Paperwork:

This regulation does not impose any new paperwork requirements.

Duplication:

This regulation does not duplicate, overlap, or conflict with relevant rules or other legal requirements of the State or federal government.

Alternatives:

An alternative to these regulatory amendments would be not to make any changes and to keep the regulations as written. However, these amendments are needed to bring the regulations into compliance with Article 25-A of the PHL, and therefore this was not considered a viable alternative.

Federal Standards:

The proposed regulations do not duplicate or conflict with any federal statutes or regulations.

Compliance Schedule:

This regulation will be effective immediately upon publication of a Notice of Adoption in the New York State Register. These proposed rules conform current regulation to existing State statutes.

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STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

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.

There was no small business or local government participation in the development of these regulations. Local government should not be impacted by these proposed regulations.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

No Rural Area Flexibility Analysis is required pursuant to section 202-bb of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed amendment that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas. These provisions apply uniformly throughout New York State, including all rural areas.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement for these 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

The New York State Department of Health (Department) proposed amendments to Part 12 of Title 10 and section 505.2(e) of Title 19 NYCRR, which were posted in the May 27th issue of the New York State Register. The intent of these amendments is to modernize the definition of abortion, to reflect the most current clinical guidance regarding abortion care, to ensure patients receiving abortion care do not undergo unnecessary treatments due to outdated laws and regulations. In addition, these changes align regulations to the terms of the Reproductive Health Act (RHA), and to ensure that health care providers are not being charged medical malpractice rates that are not justified.

During the public comment period, comments were received from three (3) stakeholders: The New York Civil Liberties Union; The American College of Obstetricians and Gynecologists (ACOG); and Planned Parenthood Empire State Acts. These comments, along with the Department's responses, are summarized below.

1. New York Civil Liberties Union (NYCLU):

The NYCLU applauds the proposed rule, which aligns the regulations with the RHA, and urges the Department to expediently finalize it. NYCLU indicated that this proposed rule would align New York's regulations with the RHA, clarify how New York law provides expansive access when a patient needs care, and remove stigmatizing and problematic language from the books.

Response: The Department appreciates New York Civil Liberties Union's comments in support of the regulatory amendments. No changes were made as a result of these comments.

2. The American College of Obstetricians and Gynecologists (ACOG):

- Removal of sections 12.13 and 12.20 of Part 12 of Title 10, regulations governing the "protection of infants and children against hazards." Striking abortion language from this regulation is important to reflect abortion as a health care service in our regulations.
- Addition of a new section 12.21 to align the determination of Rh type and administration of Rh immune globulin is in line with ACOG's evidence-based clinical guidelines.
- Amendment of section 505.2(e) of title 18 of NYCRR to update language on the types of abortion, including removal of "surgical" abortion, more accurately reflects the way care is delivered either through procedural or medication abortion.
- The removal of outdated language that limits the provision of abortion services to physicians only will bring the regulations into conformity with the Reproductive Health Act's clarification of allied health professionals' abilities to provide abortions within their scope of practice.

Response: The Department appreciates The American College of Obstetricians and Gynecologists' comments in support of the regulatory amendments. No changes were made as a result of these comments.

3. Planned Parenthood Empire State Acts.

The proposed repeal of 10 NYCRR §§ 12.13 and 12.20 and amendment of 10 NYCRR 12.20 furthers the work of Planned Parenthood by removing outdated requirements on abortion care. These proposed amendments will allow providers to practice consistent with clinical standards

and guidelines as those continue to evolve and facilitate increased access to abortion care through evolving modalities, like telehealth. Further, the retitling of this section will reduce abortion stigma by more accurately reflecting the goals and contents of the regulation.

The changes proposed to the regulations governing the standards for Medicaid coverage for abortion services are necessary to align with the Reproductive Health Act and current practice of the Medicaid program. The proposed amendments remove the requirement that only physicians may provide abortion care, in alignment with the changes made by the Reproductive Health Act and clarify the medical necessity standard for coverage within Medicaid to reflect the language used in recent years by the Office of Health Insurance Programs.

Response: The Department appreciates Planned Parenthood Empire State Acts' comments in support of the regulatory amendments. No changes were made as a result of these comments.