## SUMMARY OF EXPRESS TERMS

This regulation implements the provisions of Part L of Chapter 56 of the Laws of 2020 that are within the purview of the New York State Department of Health. Part L of Chapter 56 of the Laws of 2020, among other things, added Article 5-C to the Family Court Act (judgments of parentage of children conceived through assisted reproduction or pursuant to surrogacy agreements), amended Public Health Law Article 42 (vital statistics), added a new Article 44 to the General Business Law (regulation of surrogacy programs and assisted reproduction service providers), added a new Article 25-B to the Public Health Law (gestational surrogacy), and amended Public Health Law Article 43 (anatomical gifts).

These new provisions of law are intended to establish a parent-child relationship where the child or children is/are conceived through assisted reproduction ("Child"), and a gestational surrogate, an adult who is not an intended parent, enters into a surrogacy agreement to bear the Child resulting from an embryo formed using gametes other than the surrogate's. The Legislature directed the Department to regulate surrogacy programs and assisted reproduction service providers, the practice of gestational surrogacy, and the donation of ova to ensure the health and safety of the surrogate, the egg donor and the Child born under gestational surrogacy agreements, to ensure that the surrogacy agreement is ethical, and to ensure that surrogacy agreements are fair to the parties that enter into them.

This regulation provides a process for the licensing of surrogacy programs, the registration of gestational surrogacy assisted reproduction service providers, and the creation of a surrogacy registry and an ova registry. This regulation also implements the requirements for the Department of Health to establish gestational surrogacy guidelines and ova donation guidelines.

Pursuant to the authority vested in the Commissioner of Health by Section 1404 of the General Business Law and Sections 2599-cc and 4365(4) of the Public Health Law, the heading of Part 69 is amended and a new Subpart 69-11 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is added to read as follows, to be effective upon publication of a Notice of Adoption in the New York State Register:

The heading of Part 69 is amended to read as follows:

Part 69 – [Testing for Phenylketonuria and Other Diseases and Conditions/Early Intervention Program/Newborn Hearing Screening] <u>Family Health</u>

A new Subpart 69-11 is added to read as follows:

Subpart 69-11. Surrogacy Programs and Assisted Reproduction Service Providers

§ 69-11.1 Definitions. As used in this Part:

(a) "Assisted reproductive technology service" or "ART service" means a medical procedure intended to result in a pregnancy, including, but not limited to, in vitro fertilization (including intracytoplasmic sperm injection), embryo transfer and gamete intrafallopian transfer. This definition, for purposes of this Part, does not include artificial insemination, the process by which fresh or frozen sperm sample is introduced into a vagina other than by sexual intercourse.

(b) "Assisted reproduction service provider" means a medical provider, fertility clinic, or reproductive tissue bank (which shall include a gamete bank), or any other entity which either provides ART services in New York State or for which any component of the ART services arranged by the entity is performed in New York State.

(c) “Child” means a born individual of any age whose parentage may be determined under Article 5-C of the Family Court Act or any other law.

(d) “Donor” means an individual who does not intend to be a parent and provides reproductive tissue used for ART procedures performed on recipients other than that person or that person’s spouse, whether or not for consideration.

(e) “Health commerce system” or “HCS” shall mean the Department's secure internet portal used for communications and information exchange with organizations licensed and certified by the Department and health care providers, or any successor system used for such information exchange as required by the Department.

(f) “Intended parent” means an individual, married or unmarried, who manifests the intent to be legally bound as the parent of a Child resulting from ART or a surrogacy agreement.

(g) “Surrogate” means an adult who is not an intended parent, who enters into a surrogacy agreement to bear a Child resulting from an embryo formed using an egg other than their own.

(h) “Surrogacy program” means any person or entity licensed under this Subpart as a surrogacy program.

(1) Persons or entities who arrange or facilitate transactions contemplated in a surrogacy agreement under Article 5-C of the Family Court Act, regardless of whether such agreement ultimately comports with the requirements of Article 5-C of the Family Court Act, are required to be licensed as a surrogacy program. under this Subpart if:

(i) such person or entity is doing business in New York;

(ii) the surrogate resides in New York State during the term of the surrogacy agreement; or

(iii) any medical procedures under the surrogacy agreement are performed within New York State.

(2) A surrogacy program does not include the parties to a surrogacy agreement.

(3) For the purposes of this definition, a person or entity is considered to arrange or facilitate the transactions contemplated in a surrogacy agreement by performing any of the following acts:

(i) Planning or arranging the details of ART services with the intended parent(s);

(ii) Setting the timeline for ART services; establishing the type of ART services to be rendered; acquiring or coordinating the ART services of third-party licensed professionals;

(iii) Recruiting and/or obtaining personal information regarding surrogates;

(iv) Making, negotiating, or completing the financial arrangements for ART services;

(v) Directing, being in charge or apparent charge of, or supervising, directly or indirectly, the matching process between the intended parent(s) and surrogates;

(vi) Directing, being in charge or apparent charge of, or supervising, directly or indirectly, the ART services to be provided by another licensed person;

(vii) Using in connection with one's name or employment the words or terms "assisted reproduction," "surrogacy," or any other word, term, title, or

picture, or combination of any of the above, that when considered in the context in which used would imply that such person is engaged in the practice of surrogacy program ownership or that such person is holding themself out to the public as being engaged in the practice of providing services related to matching intended parents with surrogates; or

(viii) Managing or supervising the operation of a surrogacy program, except for administrative matters such as budgeting, accounting and personnel, maintenance of buildings, equipment and grounds, and routine clerical and recordkeeping functions.

(4) Surrogacy programs shall not include individuals or entities acting solely as gamete or embryo donor programs; escrow agents providing escrow services pursuant to a surrogacy agreement; insurance providers providing insurance pursuant to a surrogacy agreement or providing insurance review services in connection with a surrogacy arrangement; assisted reproduction service providers providing medical services pursuant to a surrogacy agreement; mental health providers providing mental health services in connection with a surrogacy arrangement; or attorneys representing a party to a surrogacy agreement.

(i) "Owner" means any and all persons who, directly or indirectly, or acting by or through one or more persons, owns a five percent or greater interest in a surrogacy program.

§ 69-11.2 Surrogacy program licensure.

(a) In order to operate a surrogacy program in New York State, a person or entity must be duly and currently licensed by the Department. As a condition for licensure, each owner shall submit to the Department, on a form and in a manner prescribed by the Department:

(1) proof of the program's professional liability insurance or other appropriate insurance coverage;

(2) the program's administrative policies and procedures, including:

(i) a conflict of interest policy satisfactory to the Department;

(ii) policies and procedures to ensure that surrogacy agreements meet the requirements of Article 5-C of the Family Court Act;

(iii) policies and procedures to ensure that the surrogate has given informed consent for the surrogacy and is afforded all of the rights set forth in and that all parties were provided with a copy of the Surrogate's Bill of Rights in Article 5-C of the Family Court Act at the time of the initial consultation;

(iv) policies and procedures to monitor parties' compliance with the terms of the surrogacy agreement, and ensure that such surrogacy agreement is in compliance with Article 5-C of the Family Court Act; and

(v) training materials for all surrogacy program staff.

(3) a background investigation report from an independent licensed private investigation company:

(i) demonstrating that the owners of the program, the individual functioning as the chief executive officer, and the individual functioning as the chief operating officer, regardless of adjudication, have never previously been

convicted or found guilty of, or entered a plea of guilty or a plea of nolo contendere to any offense involving racketeering, fraud, theft, embezzlement, fraudulent conversion, or misappropriation of property; and

(ii) specifying any judgments and liens filed with the county clerk in counties where the individuals identified in subparagraph (i) of this paragraph worked and resided and all counties contiguous to those counties (within the past 10 years); and

(4) a comprehensive credit report for each owner of the program.

(b) Each applicant shall submit to the Department any other information as may be requested under the Department's application process for licensure, including information about the owners of the program, the individual functioning as the chief executive officer, and the individual functioning as the chief operating officer, such as allegations of malpractice, actions taken against the individual's license, hospital restrictions, criminal convictions, civil and bankruptcy court actions, disputes settled through arbitration or alternative dispute resolution, whether the individual is aware of being under investigation by a governmental agency, whether a criminal charge or civil or administrative action is currently pending against the individual, and termination from employment.

(c) Changes of information.

(1) Any change in accuracy of the information provided under this section following the date of licensure and prior to renewal of licensure shall be reported to the Department.

(2) Any failure to disclose a change of information within 30 days of the change shall constitute grounds for the Department to revoke the license of such surrogacy program pursuant to section 69-11.10 of this Part.

(d) Each surrogacy program shall, as a condition of licensure, maintain and regularly monitor an account for a program owner and at least one other program official on the health commerce system.

§ 69-11.3 Surrogacy program owner information.

(a) The surrogacy program shall provide, as a condition of licensure, business and owner information to the Department such as:

(1) The business name, each business address, tax ID number, and date of incorporation if applicable;

(2) The true full legal name, date of birth, driver license number, social security or tax identification number, and home address of all owners;

(3) Degrees, certifications and licenses or other professional designation of the primary owner for the business and for all owners; and

(4) Each business or occupation engaged in by all owners during the five years immediately preceding the date of the application, including place of employment and the location thereof.

(b) Any material change in the information set forth in this section following date of licensure and prior to the annual renewal of licensure shall be reported to the Department.

(c) Any failure to disclose a material change of information within 30 days of the change shall constitute grounds for the Department to revoke the license of such surrogacy program pursuant to section 69-11.10 of this Part.

(d) When such change causes a new person to acquire a controlling interest in the surrogacy program, such person must submit an initial application for licensure before such purchase or acquisition may take place.

(e) The owner of a licensed surrogacy program is responsible for designating staff to regularly monitor and update, as needed, the surrogacy program's business and owner information.

§ 69-11.4 Surrogacy program conflicts of interest.

(a) Surrogacy programs shall, as a condition of licensure, develop and maintain policies to avoid conflicts of interest while facilitating, arranging, and engaging in the services contemplated in a surrogacy agreement.

(b) The surrogacy program's conflict of interest policy shall apply to all personnel of the surrogacy program, including but not limited to owners, employees, and contractors, who help to facilitate, arrange, or engage in any service contemplated in a surrogacy agreement.

(c) Such conflict of interest policies shall prohibit, at a minimum, the following conduct:

(1) any sort of kickback or making or receiving a referral for a fee, except for fair market value fees paid by a surrogacy program to an employee or independent contractor of the surrogacy program solely for promoting the surrogacy program and identifying potential surrogates;

(2) fee-splitting;

(3) financially benefitting from a referral, including a family member benefitting from a referral;

(4) ordering or arranging for excessive tests, treatment, or use of treatment facilities not warranted by the condition of the patient;

(5) making self-referrals, that is, referrals to health care providers with which the surrogacy program has financial relationships (other than financial relationships that would be commercially reasonable even if no referrals were made between the parties); and

(6) entering into an arrangement with a clinical laboratory under which the clinical laboratory does not directly bill the patient as required by Public Health Law section 586.

§ 69-11.5 Surrogacy program informed consent.

(a) Surrogacy programs shall obtain written informed consent from all prospective parties to the surrogacy agreement prior to entering into such agreement and shall develop and implement an informed consent form. The informed consent form shall be written in plain language and available in English, or the language the individual giving consent is most proficient in reading, and shall include, at a minimum, the following:

(1) a statement that the surrogate has been informed that their name and address will be kept on file by the surrogacy program;

(2) a statement that the surrogate has been advised of the option to voluntarily share their information with the surrogacy registry upon completion of the surrogacy agreement;

(3) HIPAA-compliant authorization for disclosure of the surrogate's relevant medical history information to prospective intended parent(s) and their physicians, consistent with statutory requirements for the disclosure of medical information;

(4) a statement that the surrogate has the right to terminate the surrogacy agreement prior to becoming pregnant by means of assisted reproduction pursuant to Article 5-C of the Family Court Act;

(5) a statement regarding the surrogacy program's screening of prospective surrogates, and the criteria assessed therein; and

(6) a copy of the Surrogates' Bill of Rights, as set forth in Article 5-C of the Family Court Act.

(b) Informed consent obtained pursuant to this section shall not constitute, or be a substitute for, informed consent to any medical procedure, medication or other medical treatment.

§ 69-11.6 Gestational surrogacy guidelines.

(a) Each surrogacy program shall, as a condition of licensure, ensure that all assisted reproduction service providers who work with surrogacy programs are registered with the Department in accordance with this Subpart.

(b) Policies and procedures for screening of gestational surrogates must be consistent with the Department's guidelines and best practices, which shall be published on the Department's website.

(c) Policies and procedures for screening and evaluation of intended parents must be consistent with clinical best practices.

(d) The Department shall develop, and make available in electronic form maintained on the Department's website, informational material relating to gestational surrogacy, which shall be made available in hard copy by the surrogacy program and at no cost to all prospective surrogates and prospective intended parents who contact the surrogacy program or seek to enter into a surrogacy agreement with the surrogacy program.

§ 69-11.7 Surrogacy registry.

(a) At such time as the surrogacy program obtains a license, the surrogacy program shall, as a condition of licensure, enroll in the Department's surrogacy registry, the central tracking registry of surrogates in New York State.

(b) Upon enrollment in the surrogacy registry, the surrogacy program shall be provided with a unique surrogacy program identifier code, which shall identify only the surrogacy program's business name and business address.

(c) Upon completion of a surrogacy agreement, the surrogacy program shall ask the surrogate whether they would like to participate in the surrogacy registry. The surrogacy program shall make such inquiry upon the completion of each new surrogacy agreement, regardless of the surrogate's prior participation in, or refusal to participate in, the surrogacy registry. The surrogate shall be provided with written informational material, written in plain language, regarding the surrogacy registry which shall indicate, at a minimum, the following:

(1) participation in the surrogacy registry is voluntary and consent can be revoked;

(2) information will be de-identified; and

(3) the surrogacy program shall adhere to all state and federal laws regarding confidentiality of private health information, and the surrogate may pursue remedies against the surrogacy program under such laws for any illegal disclosure of their confidential health information.

(d) For each surrogate, the surrogacy program shall request a unique, randomly generated surrogate identifier code from the surrogacy registry. For any surrogate who indicates, by signed acceptance maintained on file with the surrogacy program, that they wish to voluntarily participate in the surrogacy registry, upon being provided such surrogate identifier code by the Department, the surrogacy program shall:

(1) attach such code to the surrogate's confidential record maintained by the surrogacy program, or otherwise associate such code with the surrogate's confidential record, for tracking purposes; and

(2) generate a separate record, identified only with the surrogate identifier code, indicating the number of times the person associated with such code has acted as a surrogate and the health information of such surrogate, which shall at a minimum include the health screening criteria prescribed by the Department. Such unique record shall be known as the "surrogacy registry record."

(3) submit the surrogacy registry record to the Department, in a form and manner to be determined by the Department.

(e) The surrogacy program shall maintain the confidentiality of the surrogacy registry record in accordance with all applicable state and federal laws, including Public Health Law section 2599-cc(2).

§ 69-11.8 Effective date for surrogacy program licensure. Any agency, business, person or entity that is required to be licensed as a surrogacy program under this Subpart shall apply and must be approved for licensure pursuant to this Section prior to commencing operations.

§ 69-11.9 Surrogacy program licensure fees and renewals.

(a) Fees. Upon the filing of an initial application for a license pursuant to this Subpart, the owner shall pay an application fee to the Department in the amount of $1,000.

(b) Renewals. Surrogacy program licensees shall renew their license annually by submitting the information required to be submitted under this Subpart and a renewal fee in the amount of $200. Applications for renewal shall be filed with the Department, in the form and manner prescribed by the Department, 90 days prior to expiration of the current license.

§ 69-11.10 Continuation of surrogacy program licensure.

(a) Licenses are not transferable or assignable. A licensee may invalidate any license by delivering it to the Department, in the form and manner prescribed by the Department, but such delivery does not affect any civil or criminal liability or the authority to enforce this Subpart for acts committed in violation thereof.

(b) A licensee who is the subject of a voluntary or involuntary bankruptcy filing must report such filing to the Department within seven business days after the filing date.

(c) A surrogacy program’s license may be revoked, suspended, limited or annulled by the Department upon a finding that:

(1) the owner misrepresented or failed to disclose information required to be provided by this Subpart;

(2) the owner, or any employees, contractors, or other personnel under the direction and control of the surrogacy program, failed to adhere to any requirements of Article 44 of the General Business Law or this Part; or

(3) the owner, or any employees, contractors, or other personnel under the direction and control of the surrogacy program, through action or act of omission, placed parties to a surrogacy agreement or the Child intended to be born under the surrogacy agreement in danger of harm of any kind, or otherwise violated the requirements of this Subpart or any guidelines or standards required to be issued by the Department pursuant to law.

(d) No surrogacy program's license may be revoked, suspended, limited or annulled by the Department without affording the surrogacy program an opportunity to request a hearing pursuant to Part 51 of this Title.

(e) Any person or entity that is required to be licensed as a surrogacy program under this Subpart that continues to operate after the effective date of this Subpart without obtaining a license from the Department, or that continues to operate following the revocation, suspension, or annulment of their license, or that operates contrary to limitations placed on their license pursuant to this section, shall be considered to be operating a fraudulent business, and the names of the owner or owners associated therewith shall be referred by the Department to the Office of the Attorney General for investigation and possible prosecution.

§ 69-11.11 Assisted reproduction service provider registration.

(a) An assisted reproduction service provider is prohibited from performing any medical procedures for a gestational surrogacy agreement unless such assisted reproduction service provider is registered with the Department. In order to register with the Department as an assisted reproduction service provider, an assisted reproduction service provider shall provide to the Department in a form acceptable to the Department:

(1) information demonstrating that the assisted reproduction service provider is licensed to operate as a tissue bank under 10 NYCRR section 52-2.1;

(2) information regarding any other health care practitioner or health care facility licenses held by the assisted reproduction service provider or the health care practitioners who work for the assisted reproduction service provider;

(3) information regarding the assisted reproduction service provider's health commerce system account; and

(4) the types of procedures, and an estimate of the number of each type of procedure that will be performed annually, to effectuate gestational surrogacy agreements.

(b) An assisted reproduction service provider shall maintain and regularly monitor an account on the health commerce system.

(c) Assisted reproduction service providers shall establish policies and procedures relating to the selection and evaluation of prospective surrogates and the evaluation of prospective intended parents. Policies and procedures for screening of gestational surrogates must be consistent with the Department's guidelines and best practices, which shall be published on the Department's website. Policies and procedures for screening and evaluation of intended parents must be consistent with clinical best practices.

(d) Upon a change of ownership of an assisted reproductive service provider, within 30 days, such new owner shall update the information that the assisted reproductive service provider is required to submit to the Department by this Part.

§ 69-11.12 Assisted reproduction service provider conflicts of interest.

(a) The assisted reproduction service providers shall develop and maintain policies to avoid conflicts of interest while facilitating, arranging, and engaging in the services contemplated in a surrogacy agreement.

(b) The assisted reproduction service provider's conflict of interest policy shall apply to all personnel of the assisted reproduction service provider, including but not limited to owners, employees, and contractors.

(c) Such conflict of interest policies shall prohibit, at a minimum, the following conduct:

(1) any sort of kickback or making or receiving a referral for a fee under Education Law section 6530(18) or any other state or federal law;

(2) fee-splitting under Education Law section 6530(19);

(3) financially benefitting from a referral under Education Law section 6530(17);

(4) ordering or arranging for excessive tests, treatment, or use of treatment facilities not warranted by the condition of the patient under Education Law section 6530(35);

(5) making self-referrals under Public Health Law Article 2, Title 2-D; and

(6) entering into an arrangement with a clinical laboratory under which the clinical laboratory does not directly bill the patient as required by Public Health Law section 586.

§ 69-11.13 Assisted reproductive service provider informed consent and applicability of reproductive tissue bank regulations. All assisted reproduction service providers shall adhere to all applicable tissue bank regulations set forth in Part 52 of this Title, including but not limited to the informed consent requirements therein.

§ 69-11.14 Ova donation guidelines.

(a) Assisted reproduction service providers shall develop policies and procedures relating to the selection and evaluation of prospective ova donors as set forth in Part 52 of this Title.

(b) Such policies and procedures must adhere to the Department's guidelines and best practices relating to screening of ova donors, which shall be published on the Department's website.

(c) The Department shall develop and distribute, in printed and electronic form maintained on the Department's website, informational material relating to ova donation, which shall be made available by the assisted reproduction services provider in hard copy to all prospective donors who contact such provider.

§ 69-11.15 Ova donation registry.

(a) Any assisted reproduction service provider that performs ova donor evaluation and selection shall enroll in the Department's ova donation registry, the central tracking registry of ova donors in New York State who have voluntarily agreed to participate in such registry.

(b) Upon enrollment in the ova donation registry, the assisted reproduction service provider shall be provided with a unique identifier code, which shall identify only the assisted reproduction service provider's facility identification number as issued by the Department, business name, and business address.

(c) Following retrieval of oocytes from the donor who is not also the intended parent, the assisted reproduction service provider shall ask the donor whether they would like to participate in the ova donation registry. The donor shall be provided with written informational material regarding the ova donation registry which shall indicate, at a minimum, the following:

(1) participation in the ova donation registry is voluntary and consent can be withdrawn at any time;

(2) information will be de-identified; and

(3) the assisted reproduction service provider shall adhere to all state and federal laws regarding confidentiality of private health information, and the donor may pursue remedies against the assisted reproduction service provider under such laws for any unwarranted disclosure of their confidential health information.

(d) For any donor who indicates, by signed acceptance maintained on file with the assisted reproduction service provider, that they wish to voluntarily participate in the ova donation registry, the assisted reproduction service provider shall request a unique donor identifier code from the ova donation registry. Upon being provided such donor identifier code, the assisted reproduction service provider shall:

(1) attach such code to the donor's confidential record maintained by the tissue bank, or otherwise associate such code with the donor's confidential record, for tracking purposes; and

(2) generate a separate record, identified only with the donor identifier code, indicating the number of ova and the number of times ova have been donated by this particular donor, and the medical and health history of such donor, which shall include, at a minimum, all health screening criteria required under Part 52 of this Title. Such unique record shall be known as the "ova donation registry record."

(e) The assisted reproduction service provider shall maintain the confidentiality of the ova donation registry record in accordance with all applicable state and federal laws, including Public Health Law section 4365(4)(c).

## REGULATORY IMPACT STATEMENT

**Statutory Authority**:

Section 1404 of the General Business Law directs the Department of Health (Department) to promulgate regulations to implement the requirements of General Business Law Article 44 by regulating surrogacy programs and assisted reproduction service providers.

Section 2599-cc of the Public Health Law directs the Department to promulgate regulations on the practice of gestational surrogacy.

Section 4365(4) of the Public Health Law directs the Department to promulgate regulations on the donation of ova.

**Legislative Objectives**:

Part L of Chapter 56 of the Laws of 2020, among other things, added Article 5-C to the Family Court Act (judgments of parentage of children conceived through assisted reproduction or pursuant to surrogacy agreements), amended Public Health Law Article 42 (vital statistics), added a new Article 44 to the General Business Law (regulation of surrogacy programs and assisted reproduction service providers), added a new Article 25-B to the Public Health Law (gestational surrogacy), and amended Public Health Law Article 43 (anatomical gifts).

These new provisions of law are intended to establish a child's relationship to his or her parents where the child is conceived through assisted reproduction, and a gestational surrogate, an adult who is not an intended parent, enters into a surrogacy agreement to bear the child resulting from an embryo formed using eggs other than their own. The Legislature directed the Department to regulate surrogacy programs and assisted reproduction service providers, the practice of gestational surrogacy, and the donation of ova to ensure the health and safety of the surrogate, the

egg donor and the children born under gestational surrogacy agreements, to ensure that the surrogacy agreement is ethical, and to ensure that surrogacy agreements are fair to the parties that enter into them.

**Needs and Benefits**:

Licensing and regulation of surrogacy programs and assisted reproduction service providers will protect the donors, surrogates, and the children who are born under gestational surrogacy agreements. There have been documented cases in which the owners of businesses that broker surrogacy agreements have misappropriated and absconded with client funds and otherwise inadequately or negligently administered their programs to the detriment of their clients, including the donors and surrogates. These licensure requirements for surrogacy programs in New York State will reduce incompetence and fraud in the operation of businesses that arrange gestational surrogacy agreements.

Gestational surrogacy provides an opportunity for New Yorkers to become parents despite circumstances in which pregnancy is either biologically not possible or medically contraindicated. Although gestational surrogacy increases opportunities for family building, it also involves medical, psychosocial, fiscal and ethical considerations, as well as legal complexities. These regulations provide a framework to address these important considerations and establish protections for gestational surrogates and intended parents.

**COSTS:**

**Costs to Regulated Parties:**

Surrogacy programs will have to pay a $1,000 fee to become licensed and a $200 annual renewal fee, and they will incur the costs of becoming licensed. Assisted reproduction service providers are already regulated as health care providers, and this regulation will not increase their costs significantly.

It is entirely voluntary to enter into a surrogacy agreement, and this regulation will not significantly affect the cost of doing so. Rather, this regulation will help ensure that surrogacy agreements are commercially reasonable for payer and payee.

**Costs to Local Governments:**

Local governments will incur no costs under this regulation, as it will have no effect on the administration of local government.

**Costs to the Department of Health:**

The New York State Department of Health will devote the cost of approximately one grade 23 full time equivalent to the administration of this new program, which may be partially offset by the collection of surrogacy program licensing fees. The cost to the Department is the result of Laws of 2020, Chapter 56, Part L, not the implementation of the law with this regulation, which the Department is required to promulgate under Laws of 2020, Chapter 56, Part L.

**Paperwork:**

Individuals and entities wishing to become licensed as surrogacy programs under this regulation will be required to complete an application and provide information to the Department regarding their business. Surrogacy programs will be required to submit information to the Department in order for the Department to maintain the surrogacy registry, and assisted reproduction service providers will be required to register with the Department, submit information about the types and numbers of procedures performed in connection with gestational surrogacy agreements and submit information to the Department in order for the Department to maintain the ova donation registry. Such paperwork is the result of the Laws of 2020, Chapter 56, Part L, rather than these regulations.

**Local Government Mandates:**

This regulation imposes no mandates on local governments.

**Duplication:**

These regulatory amendments do not duplicate any New York State or federal rules.

**Alternatives:**

The alternative would be to not promulgate this regulation. However, this alternative would be contrary to Laws of 2020, Chapter 56, Part L, which requires the Department to promulgate this regulation. The regulation was written to impose the least burden on regulated parties and to reduce costs to the taxpayers, while protecting the health and safety of donors,

surrogates, and the parties to surrogacy agreements, as well as the children who are born under surrogacy agreements.

**Federal Standards:**

There are no federal statutes or regulations that apply to the subject matter of this regulation.

**Compliance Schedule:**

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

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## REGULATORY FLEXIBILITY ANALYSIS

**Effect on Small Business and Local Government**:

There are currently no surrogacy programs operating in New York. It is not known how many surrogacy programs will begin providing services when the Laws of 2020, Chapter 56, Part L go into effect. However, many are anticipated to be small businesses. It is also not known how many currently licensed tissue banks will choose to register as assisted reproduction service providers, but some are likely to be small businesses.

This regulation has no effect on local government.

**Compliance Requirements**:

Small businesses wishing to operate surrogacy programs and assisted reproduction service providers will be subject to the same requirements as larger businesses. They must submit information to the Department and comply with the other requirements in this regulation to become licensed. Surrogacy programs will be required to submit information to the Department in order for the Department to maintain the surrogacy registry, and assisted reproduction service providers will be required to submit information to the Department in order for the Department to maintain the ova donation registry.

**Professional Services**:

It is expected that regulated parties will need the assistance of attorneys or other consultants in order to comply with Laws of 2020, Chapter 56, Part L and this regulation, which implements that law.

**Compliance Costs**:

Surrogacy programs will have to pay a $1,000 fee to become licensed and a $200 annual renewal fee. Assisted reproduction service providers are already regulated as health care providers, and this regulation will not increase their costs significantly.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact**:

The proposed regulations are required to implement Laws of 2020, Chapter 56, Part L. They are intended to impose the least burden on regulated parties and to reduce costs to the taxpayers, while protecting the health and safety of donors, surrogates, and the parties to surrogacy agreements, as well as the children who are born under surrogacy agreements.

**Small Business and Local Government Participation:**

Stakeholders, including the American College of Obstetricians and Gynecologists (ACOG), the American Society for Reproductive Medicine (ASRM), Resolve: The National Infertility Association, and the American Bar Association, were consulted in the development of these regulations.

## RURAL AREA FLEXIBILITY ANALYSIS

**Types and Estimated Numbers of Rural Areas:**

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (https://www.census.gov/quickfacts/). At present, it is unknown how many surrogacy programs and assisted reproduction service providers will be located in these counties.

| | | |
|---|---|---|
| Allegany County | Hamilton County | Schuyler County |
| Cattaraugus County | Herkimer County | Seneca County |
| Cayuga County | Jefferson County | St. Lawrence County |
| Chautauqua County | Lewis County | Steuben County |
| Chemung County | Livingston County | Sullivan County |
| Chenango County | Madison County | Tioga County |
| Clinton County | Montgomery County | Tompkins County |
| Columbia County | Ontario County | Ulster County |
| Cortland County | Orleans County | Warren County |
| Delaware County | Oswego County | Washington County |
| Essex County | Otsego County | Wayne County |
| Franklin County | Putnam County | Wyoming County |
| Fulton County | Rensselaer County | Yates County |
| Genesee County | Schenectady County | |
| Greene County | Schoharie County | |

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010. At present, it is unknown how many surrogacy programs and assisted reproduction service providers will be located in these counties.

| | | |
|---|---|---|
| Albany County | Monroe County | Orange County |
| Broome County | Niagara County | Saratoga County |
| Dutchess County | Oneida County | Suffolk County |
| Erie County | Onondaga County | |

**Compliance Requirements**:

Individuals and entities in rural areas wishing to operate surrogacy programs and assisted reproduction service providers will be subject to the same requirements as regulated entities in non-rural areas. Such entities must submit information to the Department and comply with the other requirements in this regulation to become licensed. Surrogacy programs will be required to submit information to the Department in order for the Department to maintain the surrogacy registry, and assisted reproduction service providers will be required to submit information to the Department in order for the Department to maintain the ova donation registry.

**Professional Services**:

It is expected that regulated parties will need the assistance of attorneys or other consultants in order to comply with Laws of 2020, Chapter 56, Part L and this regulation, which implements that law.

**Compliance Costs**:

Surrogacy programs will have to pay a $1,000 fee to become licensed and a $200 annual renewal fee. Assisted reproduction service providers are already regulated as health care providers, and this regulation will not increase their costs significantly.

**Minimizing Adverse Impact**:

The proposed regulations are required to implement Laws of 2020, Chapter 56, Part L. They are intended to impose the least burden on regulated parties and to reduce costs to the

taxpayers, while protecting the health and safety of donors, surrogates, and the parties to surrogacy agreements, as well as the children who are born under surrogacy agreements.

**Rural Area Input**:

Stakeholders, including the American College of Obstetricians and Gynecologists (ACOG), the American Society for Reproductive Medicine (ASRM), Resolve: The National Infertility Association, and the American Bar Association, were consulted in the development of these regulations.

## JOB IMPACT STATEMENT

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

## SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (the Department) received comments from entities and individuals regarding the proposed amendments to Title 10 of the New York Codes, Rules and Regulations that added a new Subpart 69-11, Surrogacy Programs and Assisted Reproduction Service Providers.

The proposed amendments implement provisions of the Child-Parent Security Act. The vast majority of the comments did not question the manner in which these regulations implemented the law. Rather, the comments proposed changes to the law itself, or in some cases changes to guidance and other informational material on the Department's website. In the final rule, the Department is not making any substantive changes to the proposed regulation.

## ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (the Department) received comments from entities and individuals regarding the proposed amendments to Title 10 of the New York Codes, Rules and Regulations that added a new Subpart 69-11, Surrogacy Programs and Assisted Reproduction Service Providers. The comments and the Department's responses are summarized below.

§ 69-11.1 Definitions.

**Comment:** One commenter believes that the definition of "Surrogacy program" is too broad and ought to limit when a person or entity is considered to "arrange or facilitate the transactions contemplated in a surrogacy agreement" in section 69-11.1(h)(3).

**Response:** General Business Law Section 1400(c) states that the definition of "Surrogacy program" "does include and is not limited to any agency, agent, business, or individual engaged in, arranging, or facilitating transactions contemplated by a surrogacy agreement, regardless of whether such agreement ultimately comports with the requirements of article five-C of the family court act." The Department agrees that the regulation defines "facilitating transactions contemplated by a surrogacy agreement" broadly in section 69-11.1(h)(3), which is consistent with the definition in the General Business Law. The regulation limits the people or entities that would need to be licensed in New York State, however, in section 69-11.1(h)(1), 69-11.1(h)(2), and 69-11.1(h)(4). As a whole, the definition of "Surrogacy program" in section 69-11.1(h) makes it clear that a business must be licensed in New York as a Gestational Surrogacy Program if it is doing business in New York by matching intended parents with a gestational surrogate

who has a nexus to New York State, including, most importantly, a surrogate who resides in New York State during the term of the surrogacy agreement and/or is intending to give birth in New York State. The Department made no changes to the regulation in response to this comment.

§ 69-11.2 Surrogacy program licensure.

**Comment:** One commenter indicated the conditions for licensure should include continuing professional education and credentialing.

**Response:** Section 69-11.9(b) of the regulations requires Gestational Surrogacy Programs to renew their licenses annually. This will give the Department the opportunity to evaluate the credentials of the operators on an ongoing basis. The Department made no changes to the regulation in response to this comment.

**Comment:** Multiple commenters indicated that the policies and procedures to ensure that the person acting as surrogate has given informed consent must correspond to best medical practice. There must be procedures in place, including allowing for a reflection period if the surrogate so requires, to ensure that consent is not treated as a mere formality. There must also be specific sanctions to ensure that no undue pressure is exerted on the surrogate to consent to the surrogacy agreement or to any of its terms.

**Response:** These regulations include the informed consent requirements for the matching programs to be licensed as Gestational Surrogacy Programs. The regulations make clear in section 69-11.5(b) that informed consent obtained under these regulations "shall not constitute, or be a substitute for, informed consent to any medical procedure, medication or other medical

treatment." In addition, section 69-11.13 provides that all assisted reproduction service providers must adhere to all applicable tissue bank regulations set forth in Part 52 of this Title, including but not limited to the informed consent requirements therein. The Department agrees that gestational surrogates must give fully informed consent prior to the in vitro fertilization procedure. The Department made no changes to the regulation in response to this comment.

**Comment:** Multiple commenters indicated that DOH must establish a "complaints" mechanism and ensure that it is accessible to all parties, including surrogates, and that the Department is prepared to take enforcement actions in response to complaints.

**Response:** The Department agrees that in order to enforce these regulations, the Department will need to be able to intake complaints, and the Department's Gestational Surrogacy Program does intend to investigate complaints and enforce these regulations. A formal complaint process and form on the Department's website is under development. The Department made no changes to the regulation in response to this comment.

**Comment:** One commenter indicated that the Gestational Surrogacy Programs' policies and procedures to ensure compliance should include a clear allocation of responsibility within the surrogacy program (designation of a compliance officer) and sanctions for compliance failures.

**Response:** These regulations include the requirements for the policies and procedures of the matching programs to be licensed as Gestational Surrogacy Programs. The Gestational Surrogacy Programs will ensure that gestational surrogates in New York are fully aware of their rights under the Surrogate's Bill of Rights and that the parties to a surrogacy agreement are represented throughout the contractual process and duration of the contract and its execution by

independent legal counsel. After intended parents and gestational surrogates have been matched, the parties' independent legal counsel will have primary responsibility for ensuring compliance with Article 5-C of the Family Court Act. The Department made no changes to the regulation in response to this comment.

**Comment:** One commenter indicated the surrogate should have a designated individual in the Gestational Surrogacy Program to discuss any issues and to advocate on the surrogate's behalf.

**Response:** Gestational Surrogacy Programs are free to assign a particular individual as a point of contact to have the responsibility to advise, assist, and advocate for each of its surrogates, but the Department does not believe it is necessary to mandate this specific practice. Rather, the Department anticipates that surrogates and intended parents will have a number of different Gestational Surrogacy Programs to choose from and that each will operate and in a slightly different manner. The Department made no changes to the regulation in response to this comment.

**Comment:** One commenter indicated that the Department should require applications to become licensed as Gestational Surrogacy Programs to include allegations of medical malpractice and that section 69-11.2(b) should not merely state that such information "may be" requested by the Department.

**Response:** The Department agrees that applicants should include allegations of medical malpractice in their applications and is requiring such information to be included in the applications to become licensed and renew licensure as a Gestational Surrogacy Program. The Department made no changes to the regulation in response to this comment.

§ 69-11.5 Surrogacy program informed consent.

**Comment:** One commenter indicated that the surrogate's informed consent must be obtained in the language that the surrogate is most proficient in reading. Similarly, the consent of the other parties must also be obtained in the language in which they are most proficient.

**Response:** Section 69-11.5(a) already requires that Gestational Surrogacy Programs obtain written informed consent from all prospective parties and that the informed consent "shall be written in plain language and available in English, or the language the individual giving consent is most proficient in reading." The Department made no changes to the regulation in response to this comment.

**Comment:** One comment was regarding the fact that the surrogate must be informed that their name will be kept on file by the surrogacy program. There is no mention of keeping the name of the intended parents also on file. The commenter believes this is inequitable; both sets of names should be kept on file, and all parties should be notified accordingly.

**Response:** The Child-Parent Security Act was intended to benefit and protect both the gestational surrogates and the intended parents, but the Department believes that the Legislature crafted the law with particular focus on ensuring that surrogacy agreements do not take advantage of people who may want to become surrogates. The law and regulations are designed to make sure that people who may want to become surrogates are fully aware of the implications of agreeing to become surrogates. The Department does not think it is necessary to create such detailed requirements for the informed consent of the intended parents. The Department made no changes to the regulation in response to this comment.

**Comment:** One commenter indicated that the surrogate must be entitled to basic information about the intended parents. Therefore, a HIPAA-compliant authorization for disclosure must be obtained from the intended parents as well as from the surrogate.

**Response:** These regulations include the requirements for the policies and procedures of the matching programs to be licensed as Gestational Surrogacy Programs. The Gestational Surrogacy Programs will ensure that gestational surrogates in New York are fully aware of their rights under the Surrogate's Bill of Rights and that the parties to a surrogacy agreement are represented throughout the contractual process and duration of the contract and its execution by independent legal counsel. After intended parents and gestational surrogates have been matched, the parties' independent legal counsels will have primary responsibility for protecting the interests of the parties. The independent legal counsels for the gestational surrogates will be in a position to help the gestational surrogates learn information about the intended parents before any surrogacy agreements are executed. This may involve the execution of a HIPAA authorization by the intended parents. The Department made no changes to the regulation in response to this comment.

**Comment:** Commenters indicated that prior to entering into a surrogacy agreement, the person acting as surrogate must be provided a statement that details all of the surrogate's rights. The commenters believe that the statement should explicitly provide that the intended parents, the Gestational Surrogacy Program, and any other persons involved in the establishment or continuation of the surrogacy arrangement (including attorneys and physicians) may not exert pressure on the surrogate regarding the surrogate's right to make all health and welfare decisions

(see Family Court Act section 581-602). The surrogacy agreement should provide that the surrogate has the right to refuse conditions regarding their personal behavior during pregnancy and at childbirth, and no specific performance can be compelled in this regard. The surrogate should have the right to request information regarding the intended parents, including but not limited to the information used by the Gestational Surrogacy Program to screen prospective intended parents. The regulation should provide that the surrogate cannot be bound by a non-disclosure agreement in relation to the surrogacy agreement, nor be subjected to compulsory arbitration in case of a dispute. Also, the surrogate should be entitled to specific types of insurance, which should include disability insurance.

**Response:** The Child-Parent Security Act contains the requirements for surrogacy agreements and the specific rights that are included in the Surrogate's Bill of Rights. The Department fully supports the commenter's intent to make sure that surrogacy agreements must not take advantage of people who may want to become gestational surrogates. Nevertheless, making changes to the rights afforded to gestational surrogates would be a matter to be addressed by the Legislature and is beyond the scope of this regulation. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters noted that the surrogate may terminate the agreement prior to becoming pregnant. The commenters suggested that the regulation needs to additionally state that a surrogate may terminate the agreement by choosing to terminate the pregnancy.

**Response:** The Department agrees that under Family Court Act section 581-602, a gestational surrogate has the right to make all health and welfare decisions regarding themselves and their pregnancy, including but not limited to whether to terminate or continue the pregnancy, and

whether to reduce or retain the number of fetuses or embryos they are carrying. The regulations require that the surrogate is provided with the Surrogate's Bill of Rights, which provides that gestational surrogates have the right to end a surrogacy agreement before becoming pregnant and to make all health and welfare decisions regarding themselves and their pregnancy, including decisions to continue or end the pregnancy. The Department made no changes to the regulation in response to this comment.

§ 69-11.6 Gestational surrogacy guidelines.

**Comment:** One commenter inquired as to why only gestational surrogacy is permitted, not traditional surrogacy using the surrogate's own egg.

**Response:** These regulations implement provisions of the Child-Parent Security Act, which provides a framework for gestational surrogacy agreements. Regulation of traditional surrogacy is a matter to be addressed by the Legislature and is beyond the scope of this regulation. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters indicated concern that the risks will not adequately be communicated to surrogates. The Department's website states: "There are health risks to the surrogate as with any pregnancy." According to the commenter, there is accumulating evidence that the health risks to surrogates are greater than in a typical pregnancy and surrogates must be informed of them.

**Response:** The Department agrees that a pregnancy for gestational surrogacy is not the same as "any pregnancy." For that reason, among other things, Family Court Act section 581-402(a)(5) requires that "the person acting as surrogate has given informed consent for the surrogacy after

the licensed health care practitioner informs them of the medical risks of surrogacy including the possibility of multiple births, risk of medications taken for the surrogacy, risk of pregnancy complications, psychological and psychosocial risks, and impacts on their personal lives." The Department's website, including the "Clinical Guidelines for Assisted Reproductive Technology Service Providers for Screening of Gestational Surrogates," makes clear that the informed consent should include information about risks that would not necessarily be included for any pregnancy. These regulations make clear in section 69-11.5(b) that informed consent obtained under these regulations "shall not constitute, or be a substitute for, informed consent to any medical procedure, medication or other medical treatment." In addition, section 69-11.13 provides that all assisted reproduction service providers must adhere to all applicable tissue bank regulations set forth in Part 52 of this Title, including but not limited to the informed consent requirements therein. The Department agrees that gestational surrogates must give fully informed consent prior to the in vitro fertilization procedure. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out that the recommended age range for surrogates in the Department's "Clinical Guidelines for Assisted Reproductive Technology Service Providers for Screening of Gestational Surrogates" is 21-45, with an age of greater than 45 permitted if risks of advanced maternal age are discussed. These commenters believe that since the definition of advanced maternal age of the American College of Obstetricians and Gynecologists (ACOG) is 35, the Department's recommended range should be 21-35. These commenters believe that if the Department permits gestational surrogates to be older than 35, such gestational surrogates need to be informed about the risks of pregnancy at advanced maternal age.

**Response:** The Department's screening guidelines are a floor, not a ceiling. Gestational Surrogacy Programs may have restrictions above and beyond what is permitted under the Department's guidelines. The Department appreciates these comments and will take them into consideration as we review and update our "Clinical Guidelines for Assisted Reproductive Technology Service Providers for Screening of Gestational Surrogates." The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out that there are no medical conditions other than communicable diseases listed as disqualifying factors for potential surrogates. Comorbidities such as autoimmune disease, hypertension, and diabetes should be disqualifying.

**Response:** The Department's screening guidelines are a floor, not a ceiling. Gestational Surrogacy Programs may have restrictions above and beyond what is permitted under the Department's guidelines. As part of the screening for potential surrogates, a clinical provider will assess the overall health status and medical history, including any chronic or co-morbid conditions, and can discuss the risks of pregnancy and surrogacy within the context of the patient's health conditions. The provider and surrogate will use this information to help decide whether surrogacy is appropriate. The Department recognizes that these complex medical reviews are best handled by clinical providers who can review the patient's full medical history and record. The Department appreciates these comments and will take them into consideration as we review and update our "Clinical Guidelines for Assisted Reproductive Technology Service Providers for Screening of Gestational Surrogates." The Department made no changes to the regulation in response to this comment.

**Comment:** One commenter stated that the medical establishment has historically underestimated and undervalued the effects of pregnancy upon the human body. The commenter believes that we are finally at a cultural moment in which the disproportionate impact of birth upon the morbidity and mortality of a diverse group of women is being discussed, explored, and acknowledged. The commenter asked the Department why it would endorse new legislation that ignores this in the service of those who will not undertake any health risk.

**Response:** This comment is outside of the scope of these regulations. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters indicated it should be strongly recommended that all health-related decisions (e.g., vaccination) be made in consultation with the surrogate's independent physician.

**Response:** The Department agrees that under Family Court Act section 581-602, a gestational surrogate has the right to make all health and welfare decisions regarding themselves and their pregnancy and to consult with a physician prior to making those decisions. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out surrogates can only make decisions about health and welfare issues, not about their behavior.

**Response:** The Child-Parent Security Act contains the requirements for surrogacy agreements. The Department fully supports the commenter's intent to make sure that surrogacy agreements must not take advantage of people who may want to become gestational surrogates. Nevertheless, making changes to the rights afforded to gestational surrogates would be a matter

to be addressed by the Legislature and is beyond the scope of this regulation. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out surrogates are allowed to have non-medical cesarean section and multiple embryo transfer, which should not be permitted. The commenters stated that permitting these conflicts with ACOG recommendations and creates significant risk for surrogates and the children.

**Response:** The Department believes this comment is questioning the surrogate's right to make these decisions as provided in Family Court Act section 581-602, which would be a matter to be addressed by the Legislature and is beyond the scope of this regulation. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out these regulations do not require gestational surrogates to have disability insurance paid for by intended parents.

**Response:** The Child-Parent Security Act contains the requirements for surrogacy agreements and the specific rights that are included in the Surrogate's Bill of Rights. Family Court Act section 581-606 requires life insurance to be paid for by the intended parent or parents. The Department fully supports the commenter's intent to make sure that surrogacy agreements must not take advantage of people who may want to become gestational surrogates. Nevertheless, making changes to the rights afforded to gestational surrogates would be a matter to be addressed by the Legislature and is beyond the scope of this regulation. The Department made no changes to the regulation in response to this comment.

**Comment:** One commenter inquired as to what happens if the pregnancy results in lost employment, wages, childcare, home management, disability, or long-term impairment or loss of ability to function as a parent for the surrogate's own children.

**Response:** The Child-Parent Security Act contains the requirements for surrogacy agreements. The Department fully supports the commenter's intent to make sure that surrogacy agreements must not take advantage of people who may want to become gestational surrogates. Nevertheless, making changes to the rights afforded to gestational surrogates would be a matter to be addressed by the Legislature and is beyond the scope of this regulation. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out surrogates need to be informed that the money they receive is taxable.

**Response:** The Department agrees that this is important information for surrogates. The Gestational Surrogacy Programs will ensure that gestational surrogates in New York are represented throughout the contractual process and duration of the contract and its execution by independent legal counsel. The Department made no changes to the regulation in response to this comment.

**Comment:** One commenter indicated support for a specific bill that would amend the Child-Parent Security Act.

**Response:** This would be a matter to be addressed by the Legislature and is beyond the scope of this regulation. The Department made no changes to the regulation in response to this comment.

§ 69-11.7 Surrogacy registry.

**Comment:** Several commenters pointed out the registry should include a full reporting of all complications encountered during the surrogacy/donation process, including ovarian hyperstimulation syndrome (OHSS) and adverse pregnancy outcomes.

**Response:** This regulation implements Public Health Law section 2599-cc, which provides for a voluntary central tracking registry of persons acting as surrogates, as reported by the Gestational Surrogacy Programs. The statute requires the regulation to maintain the anonymity of the person acting as surrogate. Because the registry is voluntary and the information is reported anonymously by the Gestational Surrogacy Programs, the Department believes that the information collected could not include such a full reporting, nor does the Department believe the Legislature intended for the Department to attempt to create a registry that contains all of the information specified by the commenter. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out surrogates and egg donors should be offered the option to update their health information, including health outcomes that may relate to the procedures they underwent or that may be relevant to the future offspring they may produce.

**Response:** Because the information in the registry is reported anonymously by the Gestational Surrogacy Programs, the Department does not believe there is any mechanism that could practicably accomplish this. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out that surrogates and egg donors should be offered the option to provide information so that they may be contacted for future research.

**Response:** This comment is outside of the scope of these regulations. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out surrogates and egg donors should be offered the option to make their identities known to future offspring when they reach the age of majority.

**Response:** This comment is outside of the scope of these regulations. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out people resulting from surrogacy and egg donation should have access to their surrogate's/donor's registry data when they reach the age of majority.

**Response:** Because the information in the registry is reported anonymously by the Gestational Surrogacy Programs, the Department does not believe there is any mechanism that could practicably accomplish this. The Department made no changes to the regulation in response to this comment.

§ 69-11.11 Assisted reproduction service provider registration.

**Comment:** Several commenters stated that in general, the provisions related to assisted reproduction service providers and reproductive tissue banks need more detail and protections, similar to the sections regulating Gestational Surrogacy Programs.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, fertility clinics were already regulated both as health care providers and as tissue banks, and they continue to be so regulated. While this regulation does add some additional requirements when an assisted reproduction service provider is performing any medical procedures for a gestational surrogacy agreement, the Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates fertility clinics in general. The Department made no changes to the regulation in response to this comment.

§ 69-11.13 Assisted reproductive service provider informed consent and applicability of reproductive tissue bank regulations.

**Comment:** One commenter stated that given the litigation facing the industry surrounding the misrepresentation of donors by some cryobanks and fertility centers, there should be similar reporting requirements for fertility centers and cryobanks (broadly categorized as Assisted Reproductive Service Providers) as in section 69-11.2.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, fertility clinics were already regulated both as health care providers and tissue banks, and they continue to be so regulated. While this regulation does add some additional requirements when an assisted reproduction service provider is performing any medical procedures for a gestational surrogacy agreement, the Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates fertility centers in the way the commenter suggests. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out there is inadequate description of the informed consent process, which must include a frank discussion of known and unknown risks to current and future health.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, the Department already regulated reproductive tissue banks, and the Department continues to regulate them. The Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates reproductive tissue banks in general. The Department made no changes to the regulation in response to this comment.

§ 69-11.14 Ova donation guidelines.

**Comment:** Several commenters pointed out that there is no Egg Donors' Bill of Rights and no provision for medical coverage for complications resulting from the procedure.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, the Department already regulated reproductive tissue banks, and the Department continues to regulate them. The Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates reproductive tissue banks in general. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out there is no mention of any of the potential health risks associated with egg donation, including OHSS, possible use of general anesthesia for egg retrieval, ovarian torsion, stroke, etc.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, the Department already regulated reproductive tissue banks, and the Department continues to

regulate them. The Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates reproductive tissue banks in general. Section 69-11.13 provides that all assisted reproduction service providers must adhere to all applicable tissue bank regulations set forth in Part 52 of this Title, which already requires that donors be informed of the risks of any drugs, surgical procedures and/or anesthesia administered. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out the DOH guidance does not include a list of short- and long-term risks associated with egg donation, including the fact that there is, at present, scarce research data on long-term impact.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, the Department already regulated reproductive tissue banks, and the Department continues to regulate them. The Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates reproductive tissue banks in general. Section 69-11.13 provides that all assisted reproduction service providers must adhere to all applicable tissue bank regulations set forth in Part 52 of this Title, which already requires that donors be informed of the risks of any drugs, surgical procedures and/or anesthesia administered. The Department made no changes to the regulations in response to this comment.

**Comment:** Several commenters pointed out there is no mention of medical contraindications for egg donation, including prior history of OHSS, polycystic ovarian syndrome, endometriosis, or family history of reproductive cancers. Some commenters stated that special attention should be

given to the risk of OHSS. They stated that Department guidelines should include a recommendation for controlling the levels of hormonal stimulation to avoid the risk of OHSS, possibly including a cap on the dosage of gonadotropins administered. Commenters also noted that there is no list of recommendations, including limits on the number of oocytes retrieved, limits on the number of cycles a donor may undergo, or use of a low-stimulation protocol.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, the Department already regulated reproductive tissue banks, and the Department continues to regulate them. The Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates reproductive tissue banks in general. Section 69-11.13 provides that all assisted reproduction service providers must adhere to all applicable tissue bank regulations set forth in Part 52 of this Title. Part 52 requires that the donor's health history and results of a physical examination be reviewed as part of the donor qualification process, and that the medical director, in consultation with the medical advisory committee, develop the criteria for donation. Tissue banks are also required to have policies and procedures to implement the quality assurance and safety requirements in Part 52. The Department appreciates these comments and will take them into consideration as we review and update our "Guidelines for Assisted Reproductive Technology (ART) Service Providers – Ova Donation." The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out there is no mention of the use of eggs for research purposes; potential donors need to be informed that this is a possibility when they agree to donate their eggs.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, the Department already regulated reproductive tissue banks, and the Department continues to regulate them. The Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates reproductive tissue banks in general. In addition, section 69-11.13 provides that all assisted reproduction service providers must adhere to all applicable tissue bank regulations set forth in Part 52 of this Title, including but not limited to the informed consent requirements therein. These requirements include a provision that the donor be notified of all currently known ways in which the donor's reproductive tissue and resulting embryos may be used, and consent to such. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out the Guidelines for Assisted Reproductive Technology Service Providers states that the tissue bank "must mitigate risks to the eventual recipient(s)" of the donated egg (i.e., guard against communicable diseases) but does not mention mitigating risks to the egg donors themselves.

**Response:** The Department appreciates this comment and will take it into consideration as we review and update our Guidelines for Assisted Reproductive Technology Service Providers. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out egg donors should be given the opportunity to waive anonymity.

**Response:** Public Health Law section 4365(4) states that the registry "shall maintain the anonymity of the donor." The Department has made no changes to the regulations in response to this comment.

**Comment:** Several commenters pointed out that as in gestational surrogacy, egg donors and recipients should retain separate legal counsel to negotiate their contract, all costs to be paid by recipients.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, the Department already regulated reproductive tissue banks, and the Department continues to regulate them. The Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates reproductive tissue banks in general. The Department made no changes to the regulations in response to this comment.

**Comment:** Several commenters pointed out egg donors need to be informed that the money they receive is taxable.

**Response:** While Public Health Law section 4365(4) does give the Department broad authority to promulgate regulations on the donation of ova, the Department believes these regulations should be focused on the procedures for obtaining informed consent regarding the procedure and the disclosure of any known or potential health risks of the ova donation process. The Department does not believe it is necessary or appropriate to require tissue banks to provide information to egg donors regarding the taxability of money received for egg donation. The Department made no changes to the regulation in response to this comment.

**Comment:** One commented stated that the DOH guidelines provide an important opportunity to educate and reinforce the bright line proscribing heritable genome editing (or human germline modification). The Child-Parent Security Act does include in its definition of "gamete" a proscription on nuclear DNA that has been deliberately altered, as well as a proscription on combining nuclear DNA from one human with the cytoplasmic DNA of another human (3-person IVF). Given that use of these emerging and very controversial technologies would impact all subsequent generations, they require a robust public debate and taking every opportunity to begin this discourse is critically important.

**Response:** This comment is outside of the scope of these regulations. The Department made no changes to the regulation in response to this comment.

§ 69-11.15 Ova donation registry.

**Comment:** Several commenters pointed out that the proposal is for a voluntary Society for Assisted Reproductive Technology (SART)-type database that will include anonymous cycle-specific information. This level of information should be mandatory, as should collection of surrogates' and egg donors' prior health histories, as compiled during the screening process.

**Response:** Before the Child-Parent Security Act went into effect on February 15, 2021, the Department already regulated reproductive tissue banks, and the Department continues to regulate them. The Department does not believe the Child-Parent Security Act was intended to change the way the Department regulates reproductive tissue banks in general. The Department made no changes to the regulations in response to this comment.

**Comment:** Several commenters pointed out the registry should include a full reporting of all complications encountered during the surrogacy/donation process, including OHSS and adverse pregnancy outcomes.

**Response:** Under Public Health Law section 4365(4), the ova donation registry is voluntary and the registry must maintain the anonymity of the donor. As a result, the Department does not believe there is any mechanism by which the Department could practicably accomplish such reporting. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out surrogates and egg donors should be offered the option to update their health information, including health outcomes that may relate to the procedures they underwent or that may be relevant to the future offspring they may produce.

**Response:** Under Public Health Law section 4365(4), the ova donation registry is voluntary and the registry must maintain the anonymity of the donor. As a result, the Department does not believe there is any mechanism by which the Department could practicably collect this information. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out surrogates and egg donors should be offered the option to make their identities known to future offspring when they reach the age of majority.

**Response:** This comment is outside of the scope of these regulations. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out surrogates and egg donors should be offered the option to provide information so that they may be contacted for future research.

**Response:** This comment is outside of the scope of these regulations. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out people resulting from surrogacy and egg donation should have access to their surrogate's/donor's registry data when they reach the age of majority.

**Response:** This comment is outside of the scope of these regulations. The Department made no changes to the regulation in response to this comment.

**Comment:** Several commenters pointed out that offspring do not have rights to information from the Ova Donation Registry concerning health/medical conditions surrounding their conception/gestation/delivery.

**Response:** The information in the Ova Donation Registry is anonymous and would not contain the information specified in the comment. The Department made no changes to the regulation in response to this comment.

**Comment:** One commenter indicated the Registry should include a full reporting of all complications encountered during the gamete donation/surrogacy process, including ovarian hyperstimulation syndrome and adverse pregnancy outcomes.

**Response:** Under Public Health Law section 4365(4), the ova donation registry is voluntary, and the registry must maintain the anonymity of the donor. As a result, the Department does not believe there is any mechanism by which the Department could practicably collect this information. The Department made no changes to the regulation in response to this comment.

**Comment:** One commenter stated missing from the guidelines are any requirements as to sperm donation/registry as there are for ova donations.

**Response:** The amendment to Public Health Law section 4365 in the Child-Parent Security Act created a voluntary central tracking registry of ova donor information, but the legislation did not create a sperm donor registry. The Department made no changes to the regulation in response to this comment.

**Other Comments not related to Regulation: Birth Records**

**Comment:** Several commenters pointed out that the original birth certificate will be sealed. There is no provision for the offspring ever to have access to their original birth certificate, even upon reaching the age of majority, which is in direct contradiction to New York State adoption laws.

**Response:** This regulation did not propose any changes to the Department's regulations regarding birth records.

**Comment:** One commenter stated donor offspring's rights and entitlement to information is the same whether there is a donor ova or donor sperm who assisted in their creation.

**Response:** This regulation did not propose any changes to the Department's regulations regarding birth records.