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 who have voluntarily agreed to participate in such registry.

(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 any surrogate who indicates, by signed acceptance maintained on file with the surrogacy program, that they wish to voluntarily participate in the surrogacy registry, the surrogacy program shall request a unique, randomly generated surrogate identifier code from 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) Assisted reproductive service providers already providing ART service as of the effective date of this Subpart shall have 120 days to comply with this Part.

(e) 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. Already-existing assisted reproduction service providers as of the effective date of this regulation must comply with the regulation within 120 days.

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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.