Pursuant to the authority vested in the Commissioner of Health by section 4365 of the Public Health Law, sections 52-3.4, 52-8.1, 52-8.6 and 52-8.7 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended to read as follows, to be effective upon publication of a Notice of Adoption in the State Register:

Subdivision (c) of section 52-3.4 is amended to read as follows:

(c) All required clinical laboratory testing shall be performed by a laboratory operating under a permit issued by the department. For out-of-state tissue acquisitions by New York State-licensed banks, all required clinical laboratory testing shall be performed by a laboratory which is approved by that state's regulatory authority, the [United States Health Care Financing Administration] Centers for Medicare and Medicaid Services, or by the department.

(1) Blood samples from all allogeneic donors of tissue for clinical use, except oocyte donors tested in accordance with section 52-8.6([h]i) of this Part shall be tested for evidence of infection with HIV-1, HIV-2, hepatitis B virus (HBV), including hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) and, except for donors of eye tissue or tissue to be virally inactivated, human T-lymphotropic virus type I (HTLV-I), for purposes of donor selection. If available, aliquots of residual serum or plasma shall be frozen for retrospective testing of donors in the event that new or improved tests become available prior to the distribution of donated tissue.

* * *

Subdivision (d) of section 52-8.1 is amended to read as follows:

(d) *Client-depositor* means an [man] individual who deposits reproductive tissue prior to intended or potential use in artificial insemination or assisted reproductive procedures performed solely on [his] themself or their regular sexual partner[, or a woman who deposits reproductive tissue for processing into embryos and subsequent implantation into the same woman].

Subdivision (a) of section 52-8.6 is amended to read as follows:

(a) For reproductive tissue banks located within New York State, all required clinical laboratory testing shall be performed by a laboratory operating under a permit issued by the department. For out-of-state reproductive tissue banks, all required clinical laboratory testing shall be performed by a laboratory which is approved by that state's regulating authority, the [United States Health Care Financing Administration] Centers for Medicare and Medicaid Services, or by the department.

Subdivision (h) of section 52-8.7 is amended to read as follows:

(h) Embryos shall not be created for donation [by fertilizing donor oocytes with donor semen,] except at the request of a specific patient [who intends to use such embryos for her own treatment].

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) Article 43-B provides for regulation of tissue banks and nontransplant anatomic banks operating in or distributing tissue to New York State, and PHL § 4365 gives the Commissioner of Health the authority to promulgate regulations to establish standards for such banks.

Legislative Objectives:

The legislative objective of Article 43-B of the PHL is to provide the Department of Health the authority to regulate tissue banks in order to protect New Yorkers from the risks of transmission of infectious diseases, while ensuring safe tissue for transplant is available for patients in need. The Marriage Equality Act of 2011 granted same-sex couples the ability to enter into civil marriages. The Child-Parent Security Act of 2020 legally recognized gestational surrogacy with the intent of allowing same-sex couples to become parents more easily. In 2021, in response to changes in Insurance Law §§ 3216(l), 3221(h), 3221(k)(6), 4303(s), 4303(ll), and 4304(l), the Department of Financial Services required that New York Health Insurers cover fertility services for all New Yorkers, regardless of sexual orientation or gender identity, thereby helping protect the rights of women and LGBTQ New Yorkers. In total, there is clear legislative intent to end discrimination due to sexual orientation.

Needs and Benefits:

Most significantly, the proposed amendments remove discriminatory language that treats same-sex couples differently than heterosexual couples, consistent with the legislative intent, without increasing public health risks. The amendments also correct two instances of outdated language in the current regulation and correct a mistaken internal reference.

A client-depositor is defined in section 52-8.1(d) as a person who deposits reproductive tissue at a tissue bank for their own future use or use with their regular sexual partner. Unlike donors, client-depositors are not required to be screened or tested for infectious diseases, at increased cost and inconvenience. The current definition includes gendered terms and applies only to a man depositing semen for insemination or other assisted reproductive procedures with his partner, or a woman depositing an egg for her own future use and discriminates against women in a same-sex relationship who are providing reproductive tissue to each other in so-called “partner assisted reproduction.” As currently written, section 52-8.1 instead defines such a woman as a donor, subject to testing and screening requirements common to all donors that are not sexually intimate with the recipient, and potentially significantly increasing the costs to such women, without any benefit to public health. Amending the definition of client-depositor addresses this by removing the gendered terms and applying the definition equally to all sexually intimate couples.

The current section 52-8.7(h) precludes the creation of embryos using donor tissue except at the request of a specific recipient intending to use the embryos for her own treatment.

This is overly restrictive and contrary to current practice in reproductive medicine outside New York State, discriminates against male same-sex couples, and is contrary to New York's mandates regarding insurance coverage for fertility services and the intent of the Child-Parent Security Act (CPSA). Section 52-8.7(h) currently requires that an embryo be created only for a patient who intends to use the embryo for her own treatment. There are relatively few gestational carriers compared to need, so current practice amongst gestational surrogacy programs is to require the creation of embryos prior to the identification of a suitable gestational carrier, in order to determine that healthy, viable embryos are available. As male-male same sex couples must obviously use a donor egg to create offspring, the language of section 52-8.7(h) precludes the creation of an embryo prior to finding a gestational carrier, thereby excluding them from the benefits of fertility treatments and the CPSA's promotion of gestational carrier use. The same would also hold true for single men who desire to have a child via gestational carrier, as well as heterosexual couples with infertility diagnoses that reduce the likelihood of creation of healthy embryos.

The amendments in section 52-3.4(c) and 52-8.6(a) simply correct outdated language to accurately refer to the Centers for Medicare and Medicaid Services, and the amendment in section 52-3.4(c)(1) corrects a mistaken internal reference, which should refer to subdivision (i) rather than subdivision(h) of section 52-8.6.

Costs

Costs to Regulated Parties:

The proposed amendments will not impose costs on regulated parties.

Costs to the Agency, State and Local Governments:

The proposed amendments will not impose additional costs to the Department, the State, or to local governments.

Local Government Mandates:

The proposed amendments impose no new mandates on local governments.

Paperwork:

The proposed amendments do not require any additional record keeping requirements.

Duplication:

The proposed amendments do not duplicate or conflict with any other law, rule or regulation. The proposed amendments overlap partially with federal regulations and better align New York State's requirements with the federal requirements.

Alternatives:

The only alternative to amending the regulation would be to maintain it in its current form. However, this alternative was rejected because it would be contrary to the Child-Parent Security Act.

Federal Standards:

The US Food and Drug Administration (FDA) also regulates tissue banks. New York's tissue banking standards, found in 10 NYCRR Part 52, generally align with FDA's requirements or establish additional protections for New Yorkers, except that FDA's requirements already use gender-neutral terms and allow female partners to provide eggs to each other without being considered donors. The proposed amendment to section 52-8.1(d) better aligns New York with FDA. The proposed amendments do not exceed requirements of the Federal government.

Compliance Schedule:

The Department expects that regulated parties should be able to comply with the proposed regulation as of its effective date.

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Statement in Lieu of Regulatory Flexibility Analysis

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

Statement in Lieu of Rural Area Flexibility Analysis

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

Statement in Lieu of Job Impact Statement

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