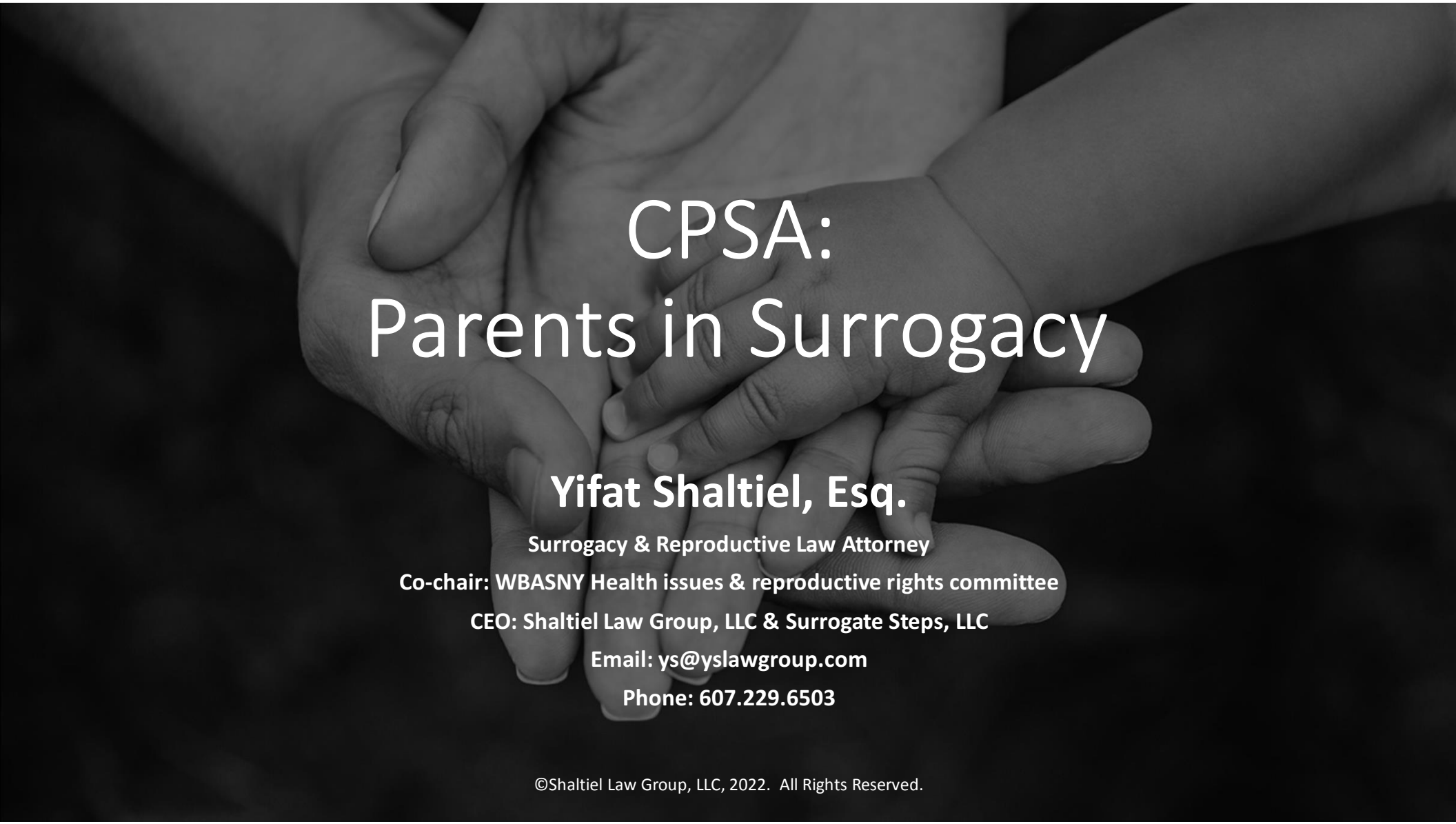

CPSA:
Parents in Surrogacy

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NY PAID SURROGACY

Ban on compensated surrogacy has been lifted in New York state.

As of February 15, 2021, compensated surrogacy is codified into law in New York.

Various forms of compensated surrogacy were introduced, including the Child Parent Security Act (CPSA). Bill finally law passed as part of the Governor's Budget.

Family Court Act, Article 5-C: Judgments of Parentage of Children Conceived Through Assisted Reproduction or Pursuant to Surrogacy Agreements.

This was driven by advancement of science and technology allowing the law to catch up with the science.

NY PAID SURROGACY

The law legalizes compensated gestational surrogacy, where there is no genetic connection between the surrogate and the child that she is carrying.

Acknowledges parentage by intent, so non-biological intended parents can be recognized as the legal parents even when using donor sperm/egg/gametes.

The Intended Parents will be legal parents by law if the surrogacy agreement meets the material requirements of the law or by Intent of the Parents.

Judgment of Parentage

May be issued prior to birth anytime after surrogacy agreement was executed

Becomes effective immediately upon birth of the child

CPSA: County

- County where parentage proceeding can be commenced:
  - County where intended parent resided any time after surrogacy agreement was executed
  - County where surrogate resided any time after surrogacy agreement was executed
  - County where child was born/resides

Parentage Petition

Petition must be Verified

Must include statement that:

- Intended Parent (at least one) is resident of NY for at least 6 months; OR
- If Intended Parent is not NY resident, that the child will be or was born in NY state within 90 days of filing

Petition for Judgement of Parentage

Must include certification from attorney for intended parent, and attorney for surrogate that requirements of Part 4 of CPSA Art. 5 of Family Court Act (CPSA) have been met.

Must include a statement from all parties that the surrogacy agreement was executed knowingly and voluntarily and that all parties are jointly requesting the judgment of parentage

CPSA: Judgement of Parentage

If requirements are met, judgement of parentage includes:

(1) declaring, that upon the birth of the child born during the term of the surrogacy agreement, the intended parent or parents are the only legal parent or parents of the child;

(2) declaring, that upon the birth of the child born during the term of the surrogacy agreement, the person acting as surrogate, and the spouse of the person acting as surrogate, if any, is not the legal parent of the child;

(3) declaring that upon the birth of the child born during the term of the surrogacy agreement, the donors, if any, are not the parents of the child;

(4) ordering the person acting as surrogate and the spouse of the person acting as surrogate, if any, to transfer the child to the intended parent or parents if this has not already occurred;

5) ordering the intended parent or parents to assume responsibility for the maintenance and support of the child immediately upon the birth of the child; and

CPSA: Judgement of Parentage

- If certification that requirements of part four of CPSA cannot be made because of technical or non-material deviation rom the requirements of the CPSA, the Court may still enforce the agreement and issue a judgment of parentage if:
  - Court determines the agreement is in substantial compliance with the requirements of the CPSA; OR
  - If surrogacy agreement does not meet material requirements of CPSA, then court can determine parentage based on intent of the parties, taking into consideration the best interests of the child. (Intended parent's absence of genetic connection to the child is not a sufficient basis to deny parentage).

CPSA: Surrogacy Agreement

- CPSA lists several requirements for the surrogacy agreement:
  - Surrogate must be 21 years of age
  - Citizenship/Residency
  - Informed Consent
  - Insurance (Medical; Life; Disability)
  - Independent Escrow
  - Independent Attorney representation
  - Meet DOH guidelines
  - Surrogate must have received Bill of Rights

Intended Parents Marital Status

- To enter into an enforceable surrogacy agreement, at time of execution of the agreement the Intended Parents must be:
  - A single adult not in a spousal relationship;
  - Two spousal adults together (legal relationship e.g. married/civil union/domestic partnership);
  - Any two adults who are intimate partners together (not married but intimate);
  - One adult in a spousal (legal) relationship but:
    - They are living separate and apart pursuant to decree or judgment of separation or a recorded written separation agreement; or
    - They have been living separate and apart for at least 3 years prior to execution of the surrogacy agreement
    - Non-participating spouse will not be acknowledged as the Intended Parent. (But if using non-participating spouse's genetics, then it can get very messy).

Divorce of Intended Parents

Surrogacy agreement must provide that the intended parents agree to be responsible for the support of all resulting children immediately upon birth.

If Intended Parents execute and enter into an enforceable surrogacy agreement, then a separation or divorce of the Intended Parents will not affect the Intended Parents rights, duties and responsibilities that they have to the surrogate and to the child that was conceived.

Example: Parents will still be (jointly and severally) responsible for all obligations and responsibilities agreed to in regards to the surrogate, and upon birth of the child they will both be responsible to support the resulting child.

Citizenship/Residency

To enter into an enforceable surrogacy agreement, at time of execution of the agreement citizenship/residency requirements must be met:

Surrogate must be US Citizen or Lawful permanent resident, and must be resident of NY for at least 6 consecutive months.

At least one of the intended parents must be US citizen or a lawful permeant resident AND that intended parent must have been a resident of NY for at least 6 consecutive months.

Compensation

Surrogate may be compensated.

Compensation is for medical risks that surrogate is taking, physical discomfort, inconvenience and the responsibilities she is undertaking in connection with the surrogacy arrangement.

Compensation cannot be conditioned on outcome, such as quality of embryos, birth of child, or a healthy child.

Compensation must be placed in escrow prior to start of medication.

Final payment must be made no later than 8 weeks post-delivery.

No minimum compensation, it is negotiated between the parties. Should be in good faith.

Eligibility of Surrogate

To enter into an enforceable surrogacy agreement the surrogate at time of execution of the agreement must:

Be at least 21 years old.

Meet citizenship and residency requirement.

Must be gestational carrier, and not traditional.

Must pass medical evaluation by health care practitioner relating to the anticipated pregnancy, including screening of her medical history and evaluation of known health conditions that may pose risks to the potential pregnancy or embryo during the pregnancy.

Eligibility of Surrogate

Must give her ”informed consent” to be a surrogate after she has been informed of the medical risks of surrogacy, including possibility of multiple births, risks due to medication, complications of pregnancy, psychological and psychosocial risks and how it might impact her personal life.

Must have been represented (as well as her spouse if applicable) by independent counsel licensed to practice law in NY, and paid for by the intended parents.

Health Insurance.

Life Insurance.

Health Insurance for Surrogate

Surrogate must have comprehensive health insurance policy that takes effect prior to start of medication or prior to any treatment for an embryo transfer.

Health insurance must cover preconception care, prenatal care, major medical treatments, hospitalization, and behavioral health care.

Policy has to be for a "term" that extends throughout the duration of the surrogacy pregnancy and for 12 months post pregnancy.

Intended parents pay for the premiums, deductible, co-pays, and out-of-pocket expenses.

- A Compassionate Surrogate may waive payments by the Intended Parents.

Life Insurance for Surrogate

Surrogate must have life insurance in place prior to start of medication or prior to any treatment for an embryo transfer.

Life insurance must provide coverage of a minimum of $750K for the benefit of a beneficiary that the surrogate designates, or if she is not eligible for $750K, then the maximum amount that she is eligible for.

Policy has to be for a "term" that extends throughout the duration of the surrogacy pregnancy and for 12 months post pregnancy.

Policy must be paid for by Intended Parents (directly, via reimbursements, or other means).

- A Compassionate Surrogate may waive payments by the Intended Parents.

Disability Insurance for Surrogate

Surrogate has a right to request that the intended parents procure and pay for disability insurance policy for the surrogate.

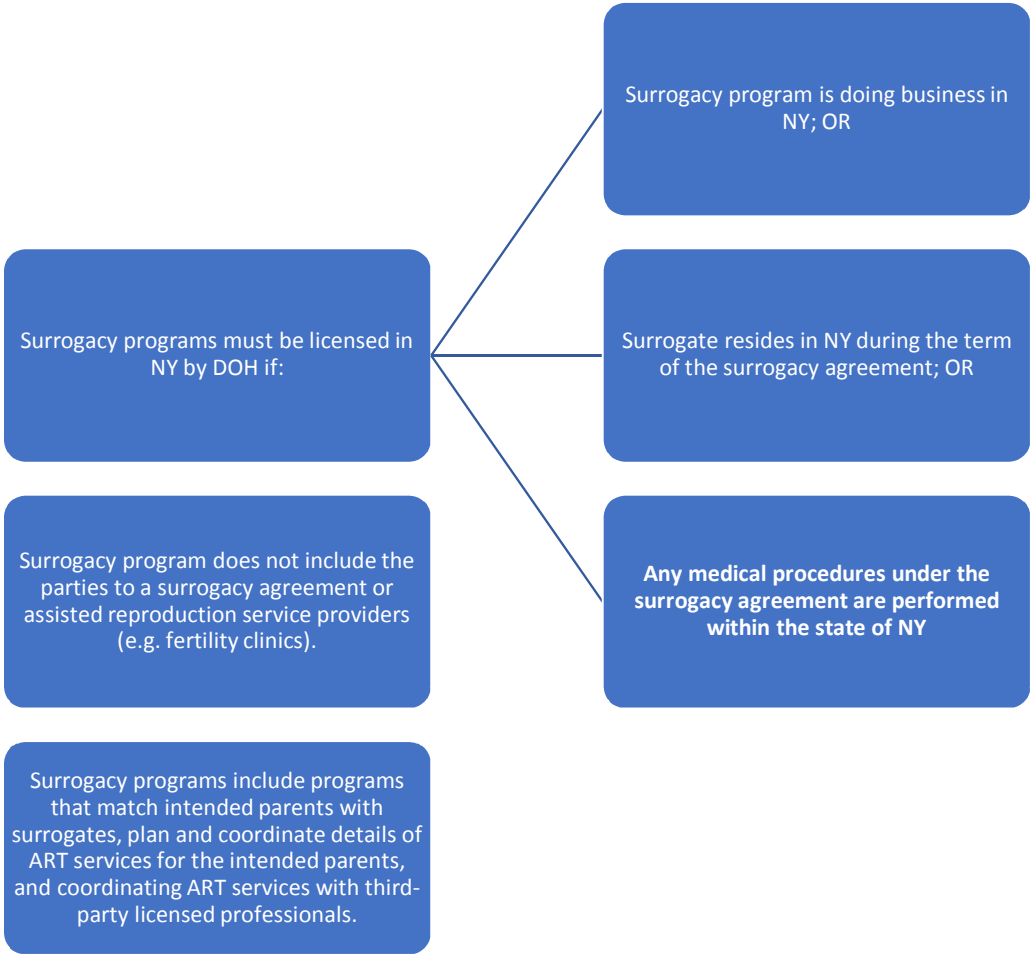
Surrogate may designate the beneficiary of the policy.

Intended parents must pay for the disability insurance policy if such policy is requested by the surrogate.

Last Will and Testament

Execute	Intended parents must execute a Will prior to the embryo transfer.
Designate	The Will must designate a legal guardian for all resulting children.
Authorize	The Will must authorize their executor to perform the intended parent's obligations pursuant to the surrogacy agreement.

Surrogacy Programs Regulations



Surrogates' Bill of Rights

- **Surrogates' Bill of Rights include:**
  - The right to make her own health and welfare decisions, including agreeing to C-section, multiple embryo transfer, choosing her own health care providers, and terminating or continuing with the pregnancy.
  - The right to have her own independent counsel
  - The right to have health insurance and medical costs coverage
  - The right to obtain counseling
  - The right to have life insurance coverage
  - The right to terminate a surrogacy agreement prior to pregnancy

Questions:

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CHILD PARENT SECURITY ACT (CPSA)

MELISSA B. BRISMAN, ESQ.

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NY CPSA COMPLIANCE & PARENTAGE ORDER

JUDGMENT OF PARENTAGE

(A) PROCEEDING MAY BE COMMENCED

- IN ANY COUNTY WHERE INTENDED PARENT(S) RESIDED ANY TIME AFTER SURROGACY AGREEMENT WAS EXECUTED

- IN THE COUNTY WHERE CHILD WAS BORN OR RESIDES

- IN THE COUNTY WHERE SURROGATE RESIDED ANY TIME AFTER SURROGACY AGREEMENT WAS EXECUTED

(B) PROCEEDING MAY BE COMMENCED AT ANY TIME AFTER SURROGACY AGREEMENT HAS BEEN EXECUTED. SURROGATE AND INTENDED PARENT(S) ARE NECESSARY PARTIES.

(C) PETITION FOR A JUDGMENT OF PARENTAGE MUST BE VERIFIED AND INCLUDE:

- A STATEMENT THAT SURROGATE OR AT LEAST ONE INTENDED PARENT HAS BEEN A RESIDENT OF NY FOR AT LEAST 6 MONTHS AT THE TIME SURROGACY AGREEMENT WAS EXECUTED; AND

- A CERTIFICATION FROM ATTORNEY REPRESENTING INTENDED PARENT(S) AND ATTORNEY REPRESENTING SURROGATE THAT REQUIREMENTS OF CPSA HAVE BEEN MET; AND

- A STATEMENT FROM ALL PARTIES THAT EACH VOLUNTARILY ENTERED SURROGACY AGREEMENT AND THAT THEY ARE JOINTLY REQUESTING A JUDGMENT OF PARENTAGE.

SUBSTANTIAL COMPLIANCE

THE COURT MAY NEVERTHELESS ENFORCE THE AGREEMENT AND ISSUE A JUDGMENT OF PARENTAGE IF THE COURT DETERMINES THE AGREEMENT IS IN SUBSTANTIAL COMPLIANCE WITH THE REQUIREMENTS OF CPSA

INSUFFICIENT AGREEMENT

IF A SURROGACY AGREEMENT DOES NOT MEET THE MATERIAL REQUIREMENTS OF THIS ARTICLE, THE AGREEMENT IS NOT ENFORCEABLE AND THE COURT SHALL DETERMINE PARENTAGE BASED ON THE INTENT OF THE PARTIES, TAKING INTO ACCOUNT THE BEST INTERESTS OF THE CHILD. AN INTENDED PARENT'S ABSENCE OF GENETIC CONNECTION TO THE CHILD IS NOT A SUFFICIENT BASIS TO DENY THAT INDIVIDUAL A JUDGMENT OF LEGAL PARENTAGE.

LACK OF SURROGACY AGREEMENT

WHERE THERE IS NO SURROGACY AGREEMENT, THE PARENTAGE OF THE CHILD WILL BE DETERMINED BASED ON OTHER LAWS OF THIS STATE.

WHAT JUDGMENT OF PARENTAGE DECLARES/ORDERS

- UPON THE BIRTH OF CHILD, INTENDED PARENT(S) IS RECOGNIZED AS THE ONLY LEGAL PARENT OF CHILD;
- SURROGATE (AND SPOUSE) IS NOT THE LEGAL PARENT OF CHILD;
- DONOR(S), IF ANY, IS NOT THE LEGAL PARENT OF CHILD;
- SURROGATE (AND SPOUSE) TO TRANSFER CUSTODY OF CHILD TO INTENDED PARENT(S) IF THIS HAS NOT ALREADY OCCURRED;
- INTENDED PARENT(S) TO ASSUME RESPONSIBILITY FOR MAINTENANCE AND SUPPORT OF CHILD IMMEDIATELY UPON BIRTH; AND

(I) ORDERS CLERK OF THE COURT TO TRANSMIT TO DOH ON A FORM PRESCRIBED BY THE COMMISSIONER, WRITTEN NOTIFICATION OF ENTRY OF THE ORDER, TOGETHER WITH SUCH OTHER FACTS AS MAY ASSIST IN IDENTIFYING BIRTH RECORD OF THE PERSON WHOSE PARENTAGE WAS IN ISSUE; AND

(II) UPON RECEIPT OF A JUDGMENT OF PARENTAGE, LOCAL REGISTRAR WHERE CHILD WAS BORN WILL REPORT THE PARENTAGE OF CHILD TO APPROPRIATE DOH IN CONFORMITY WITH THE COURT ORDER. IF AN ORIGINAL BIRTH CERTIFICATE HAD ALREADY BEEN ISSUED, THE APPROPRIATE DOH WILL AMEND THE BIRTH CERTIFICATE IN AN EXPEDITED MANNER AND SEAL THE PREVIOUSLY ISSUED BIRTH CERTIFICATE.

CHOICE OF LAW

- INTENDED PARENT(S) LIVES OUTSIDE NEW YORK STATE IN A SURROGATE FRIENDLY STATE
- SURROGATE DELIVERS OUTSIDE NEW YORK STATE
- USE LAW OF STATE WHERE AGENCY AND/OR CLINIC LOCATED TO GOVERN THE AGREEMENT AND PARENTAGE ORDER

FULL FAITH AND CREDIT

- UNDER CPSA, PARENTAGE ORDER OF ANOTHER STATE WILL BE GIVEN FULL FAITH AND CREDIT BY THE STATE OF NEW YORK

CASES POST ENACTION OF THE CPSA

- DEPENDS ON THE JUDGE
- BOROUGH
- FAMILY COURT OR SUPREME COURT

CASES WHERE SURROGACY WAS ENTERED INTO PRIOR TO CPSA

- AGAIN UP TO THE JUDGE
- VERY COURT SPECIFIC

TAKE AWAYS

- IT MAY BE IN THE BEST INTEREST OF INTENDED PARENT(S) TO OBTAIN JUDGMENT OF PARENTAGE BASED ON THE INTENTION OF THE PARTIES AND NOT BASED ON AN ENFORCEABLE NY SURROGACY AGREEMENT; OR
- IT MAY BE IN THE BEST INTEREST OF INTENDED PARENT(S) TO NEGOTIATE AND EXECUTE A SURROGACY AGREEMENT BASED ON THE LAW OF A FRIENDLY SURROGATE STATE, WHERE ONE PARTY RESIDES (OTHER THAN NY); WHERE THE AGENCY, CLINIC, AND/OR DONOR IS LOCATED AND OBTAIN THE JUDGMENT OF PARENTAGE IN THAT STATE
    - ONCE THE JUDGMENT IS OBTAINED IN THE OTHER STATE, PRESENT THAT SISTER STATE'S ORDER FOR ENFORCEMENT IN NEW YORK

FAMILY COURT OF THE STATE OF NEW YORK
COUNTY OF [redacted]

IN THE MATTER OF A PARENTAGE PROCEEDING

[redacted] **and**
[redacted]**,**
Petitioners,

-against-

[redacted] **and**
[redacted]**,**
Respondents.

ORDER AND JUDGMENT

PARENTAGE

Docket No. _____

NOTICE: Pursuant to Family Court Act §1113, an appeal must be taken within 30 days of the receipt of this order by the appellant in court, 35 days from the mailing of the order to the appellant by the Clerk of the Court, or 30 days after service by a party or attorney for the child upon the appellant, whichever is earliest.

WHEREAS, the Petitioners [redacted] and [redacted], who are residents of New York State for six (6) consecutive months, filed a Petition with this Court verified the [redacted], as Intended Parents requesting a Declaration of Parentage recognizing the Petitioners as the legal and genetic parents of the Child, named [redacted], being carried by a person acting as the surrogate, [redacted], who is a New York Resident and has been a New York resident for six (6) consecutive months, and plans on delivering the Child in the County of [redacted] on or about [redacted]; and

WHEREAS, Petitioners Intended Parents, [redacted] and [redacted], executed affidavits on [redacted] supporting the Petition for Declaration of Parentage to recognize Petitioners as the legal mother and father of the subject Child, [redacted]; and

WHEREAS, Respondents, [redacted] and [redacted], the person acting as a surrogate and her spouse, executed affidavits on [redacted] acknowledging that Respondent [redacted] acted as a compassionate uncompensated surrogate for the Petitioners Intended Parents, and that the both Respondents fully support the Petitioners' Petition and reliefs requested therein; and

WHEREAS, [redacted], reproductive endocrinologist and Director of [redacted] (hereinafter "Fertility Clinic"), located at [redacted], executed an affidavit on [redacted], establishing the chain of custody of Petitioners Intended Parents' embryos, and that the Child, [redacted], is the genetic Child of the Petitioners Intended Parents, created [redacted] gametes, and that the Child is not genetically related to the surrogate or her spouse ; and

WHEREAS, on [redacted], the Parties knowingly and voluntarily entered into and executed a surrogacy agreement; and

WHEREAS, on [redacted], the Parties respective attorneys filed a certification that the requirements of part four of Article 5-C of the Family Court Act have been met; and

WHEREAS, this Court taking the requirements of Article 5-C of the Family Court Act into consideration, and based on the intent of the Parties, and taking into account the best interest of the Child, that this Court determines a judgment of legal parentage in favor of the Intended Parents, the Petitioners herein:

NOW, IT IS HEREBY

ORDERED ADJUDGED AND DECREED, that upon birth of the Child, [redacted], born during the term of the surrogacy arrangement and/or agreement, the Intended Parents, [redacted] and [redacted], are the only legal parents of the Child [redacted]; and it is further

ORDERED ADJUDGED AND DECREED, that upon birth of the Child, [redacted], born during the term of the surrogacy arrangement and/or agreement, the person acting as a Surrogate, [redacted], and her spouse, [redacted], are not the legal parents of the Child, [redacted]; and it is further

ORDERED ADJUDGED AND DECREED, that upon birth of the Child, [redacted], born during the term of the surrogacy arrangement and/or agreement, the donors, if any, are not the parents of the Child, [redacted]; and it is further

ORDERED ADJUDGED AND DECREED, that upon birth of the Child, [redacted], the person acting as a Surrogate, [redacted], and her spouse, [redacted], shall transfer the Child, [redacted], to the Intended Parents, [redacted] and [redacted]; and it is further

ORDERED ADJUDGED AND DECREED, that the Intended Parents, [redacted] and [redacted], shall assume responsibility for the maintenance and support of the Child immediately upon the birth of the [redacted]; and it is further

ORDERED ADJUDGED AND DECREED that it is hereby directed that the Child's birth certificate be issued in conformity with this Order and Judgment; and it is further

ORDERED ADJUDGED AND DECREED, that pursuant to section two hundred fifty-four of the judiciary law, the clerk of the court shall transmit to the state commissioner of health, or for a person born in New York city, to the commissioner of health of the city of New York, on a form prescribed by the commissioner, a written notification of such entry together with such other facts as may assist in identifying the birth record of the person whose parentage was in issue and, if the person whose parentage has been determined is under eighteen years of age, the clerk shall also transmit to the registry operated by the department of social services pursuant to section three hundred seventy-two-c of the social services law a notification of the determination; and it is further

ORDERED ADJUDGED AND DECREED, that pursuant to section forty-one hundred thirty-eight of the public health law (and NYC Public Health Code section 207.05) that upon receipt of a judgement of parentage the local registrar where a child is born will report the parentage of the child to the appropriate department of health in conformity with the court order. If an original birth certificate has already been issued, the appropriate department of health will amend the birth certificate in an expedited manner and seal the previously issued birth certificate except that it may be rendered accessible to the child at eighteen years of age or the legal parent or parents.

ORDERED ADJUDGED AND DECREED that a true certified copy of this Order and Judgment together with any incorporated documents in this Order and Judgment shall be provided to all parties and respective counsel.

ENTER:

Dated: _____, 2022

_____
HON.
FAMILY COURT JUDGE

Recommendations for gamete and embryo donation: a committee opinion

The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology

American Society for Reproductive Medicine and Society for Assisted Reproductive Technology, Birmingham, Alabama

This document provides the latest recommendations for evaluation of potential sperm, oocyte, and embryo donors, incorporating recent information about optimal screening and testing for sexually transmitted infections, genetic diseases, and psychological assessments. This revised document incorporates recent information from the U.S. Centers for Disease Control and Prevention, the US Food and Drug Administration, and the American Association of Tissue Banks, with which all programs offering gamete and embryo donation services must be thoroughly familiar, and replaces the document titled, "2008 Guidelines for Gamete and Embryo Donation: A Practice Committee Report," last published in Fertil Steril 2008;90:S30–44. (Fertil Steril® 2013;99:47–62. ©2013 by American Society for Reproductive Medicine.)

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Use your smartphone to scan this QR code and connect to the discussion forum for this article now.*

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The 2012 Recommendations for Gamete and Embryo Donation provide the latest recommendations for evaluation of potential sperm, oocyte, and embryo donors, incorporating recent information about optimal screening and testing for sexually transmitted infections (STIs), genetic diseases, and psychological assessments. The current document represents an effort to make the screening guidelines for donors of embryos and gametes more consistent and incorporates recent information from the US Centers for Disease Control and Prevention (CDC), US Food and Drug Administration (FDA), and American Association of Tissue Banks (AATB). The risks for transmission of STIs via donations of sperm, oocytes, and embryos differ, and leukocyte-rich semen donation poses unique risks that are reflected in the recommendations.

These guidelines use terminology from the federal agencies in addition to the AATB. In that context, the term "screening" refers to specific historical factors that place an individual at a higher risk for a given disease, such as human immunodeficiency virus (HIV), transmissible spongiform encephalopathy (TSE), or Creutzfeldt-Jakob disease (CJD). "Testing" refers to specific laboratory studies such as serologic tests. The distinction between screening and testing is consistent within the document.

These guidelines for the screening and testing of gamete and embryo donors apply to potential donors in the United States. Because the prevalence of STIs and genetic diseases may vary in other locales, these guidelines may not be appropriate for other countries or individuals who come to the United States from other countries. Whereas the FDA does not require screening or testing of the recipients of donated gametes, the American Society for Reproductive Medicine (ASRM) recommends testing of recipients as described. Other areas where the ASRM recommendations may be more stringent than the FDA minimum requirements are noted in the text. Additionally, state requirements may be more restrictive than the FDA, and clinics are encouraged to check with government officials in the state where their practice is located to determine minimum screening and testing requirements for their state.

The promulgation of FDA regulations has added considerable oversight to gamete and embryo donation, including mandatory registration of all assisted reproductive technology (ART) programs with the federal government, federal inspections of programs that are performing donation, required documentation, and written

Received September 19, 2012; accepted September 21, 2012; published online October 22, 2012.
No reprints will be available.
Correspondence: Practice Committee, American Society for Reproductive Medicine, 1209 Montgomery Hwy., Birmingham, AL 35216 (E-mail: ASRM@asrm.org).

Fertility and Sterility® Vol. 99, No. 1, January 2013 0015-0282/$36.00

http://dx.doi.org/10.1016/j.fertnstert.2012.09.037

protocols attendant to donor screening, testing, selection, rejection, and follow-up. Complete records of all donor cycles, including documentation of adherence to FDA regulations, must be made available to FDA inspectors at their request. Federal regulations may be viewed at the following Web sites:

http://www.fda.gov/cber/tiss.htm
http://www.fda.gov/BiologicsBloodVaccines/default.htm
http://www.fda.gov/cber/rules/gtp.pdf

GUIDELINES FOR SPERM DONATION

I. Introduction

Therapeutic donor insemination (TDI) may be used to achieve pregnancy where appropriate indications exist. The clinical procedures should take into account the age and health status of the recipient. The FDA has published requirements for the screening and testing of donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps), which are included here. These are the minimum requirements mandated by the federal government. In some instances, the federal requirements may be less rigorous than those in the state in which an individual practice is located or than those recommended by ASRM and the Society for Assisted Reproductive Technology (SART). It is the responsibility of all clinics to know the regulations of their individual states and local municipalities and to comply with those standards.

II. Indications for TDI

A. The male partner has azoospermia, severe oligozoospermia, or other significant sperm or seminal fluid abnormalities.
B. The male partner has ejaculatory dysfunction.
C. The male partner demonstrates significant male factor infertility (i.e., significant oligoasthenospermia or prior failure to fertilize after insemination in vitro and intracytoplasmic sperm injection [ICSI] is not elected or feasible).
D. The male partner has a significant genetic defect or the couple previously has produced an offspring affected by a condition for which carrier status cannot be determined.
E. The male partner has a sexually transmissible infection that cannot be eradicated.
F. The female partner is Rh-negative and severely Rh-isoimmunized and the male partner is Rh-positive.
G. Females without male partners.

III. Psychological consultation for recipients

The decision to proceed with donor insemination is complex, and patients and their partners (if applicable) may benefit from psychological counseling to aid in this decision. The clinician should strongly recommend psychological counseling by a qualified mental health professional to all donor sperm recipients and their partners. The assessment should include a clinical interview and, where appropriate, psychological testing. The clinician should require psychological consultation for couples in whom factors appear to warrant further evaluation. In cases of directed donation, the potential impact of the relationship between the donor and recipient should be explored, as well as any plans that may exist relating to disclosure and future contact.

IV. Evaluation of the partner

A. The partner in any couple that requests TDI should have completed an appropriate clinical evaluation. Medical records should be reviewed before performing the insemination procedure. If appropriate, alternative treatments should be discussed with the couple. While not required by the FDA, infectious disease testing of the male partner is recommended by the ASRM to address any potential medical/legal issues that could arise should the partner seroconvert during or after TDI.
B. Human immunodeficiency virus (HIV-1 antibody [AB] and nucleic acid testing [NAT]), HIV-2 AB testing and screening, or testing for HIV group O antibodies on the male partner is strongly recommended. If the male partner is HIV infected, he should be referred to an appropriate infectious disease specialist for counseling on safe sex practices for preventing HIV transmission, on treatment options, and on other issues concerning HIV disease. A positive HIV test result for the male partner should not be used as an exclusionary criterion for treatment of a couple with TDI.
C. Testing for other STIs similar to that recommended for the female partner (detailed in section V) is encouraged. This includes:
   1. Serologic test for syphilis.
   2. Hepatitis B surface antigen.
   3. Hepatitis B core antibody (IgG and IgM).
   4. Hepatitis C antibody and NAT.
   5. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the urethral meatus.

   Note: There are no FDA-licensed, approved, or cleared tests for donor screening of these organisms in an asymptomatic, low-prevalence population. Tests using NAT technology adequately and appropriately reduce the risk of transmission of these relevant communicable agents.
   6. Human T-cell lymphotropic virus (HTLV) type I and II also may be obtained at the discretion of the clinician in the appropriate clinical setting.

V. Evaluation of the female recipient

A. Routine medical and reproductive history should be obtained according to the standards that are applied to women anticipating pregnancy. Abnormalities detected from history or physical examination may require more detailed evaluation and treatment before proceeding with insemination.
B. A complete general physical examination should be performed, including a pelvic examination.
C. Standard preconceptional screening, testing, and counseling:
   1. Although there are no federal requirements for testing donor sperm recipients, the following tests are recommended:
      a. Blood type, Rh factor, and antibody screen.

b. Rubella and varicella titers. Vaccination should be offered if the individual is not immune to either virus.
c. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the cervix, urethral meatus, or vagina.
d. HIV-1 (AB and NAT), HIV-2 AB testing, and testing or screening for HIV group O antibodies should be performed to address potential medical/legal complications that could arise if the recipient seroconverts during or after treatment. In addition, if the female recipient is found to be HIV-infected before treatment, she should be referred to an appropriate infectious disease specialist for counseling on issues concerning HIV disease, including reproductive issues such as safe sex practices for preventing HIV transmission to uninfected partners and treatment options to reduce the probability of transmission to her child. A positive HIV test of the female recipient should not be used as an exclusionary criterion for treatment with TDI as long as the couple makes an informed decision after counseling and agrees to comply with recommended clinical management for the positive HIV status during pregnancy.
e. Serologic test for syphilis.
f. Hepatitis B surface antigen.
g. Hepatitis B core antibody (IgG and IgM).
h. Hepatitis C antibody and NAT.
i. Cytomegalovirus (CMV) antibody (IgG and IgM). For women who test positive for active infection (positive urine or throat culture or paired serum samples demonstrating a four-fold rise in IgG antibody and IgM antibody at least 30% of the IgG level), attempts to conceive should be postponed until they no longer exhibit active infection, owing to the risk of transmitting the infection to their fetus and the serious potential consequences of fetal CMV infection.
j. HTLV type I and II also may be obtained at the discretion of the clinician in the appropriate clinical setting.

D. Documentation and timing of ovulation
1. Women with regular cyclic menses and molimina are assumed to be ovulating. When doubt exists, an index of ovulation, such as serum progesterone level, basal body temperature recordings, LH surge detection, and ultrasound monitoring of follicular maturation, may be used to document ovulation. Appropriate timing of the insemination procedure optimizes chances for success.

E. Evaluation for possible tubal or peritoneal abnormalities

F. Patients who fail to conceive after 4 to 6 well-timed inseminations may be candidates for hysterosalpingography (HSG), laparoscopy, or other appropriate tests to detect possible causes for their failure to conceive. Pretreatment HSG or laparoscopy may be indicated by the history and/or physical findings.

G. Informed consent should be obtained from the patient (and her partner, if applicable).

VI. Donors

A. Selection of donor
1. The main qualities to seek in selecting a donor for TDI are an assurance of good health status and the absence of known genetic abnormalities.
2. The donor should be of legal age and, ideally, less than 40 years of age.
3. Selection of donors with established fertility is desirable but not required.
4. Psychological evaluation and counseling by a qualified mental health professional is strongly recommended for all sperm donors. The assessment should include a clinical interview and, where appropriate, psychological testing. Psychological consultation should be required for individuals in whom there appear to be factors that warrant further evaluation. In cases of directed donation, psychological evaluation and counseling are strongly recommended for the donor and his partner (if applicable) as well as for the recipient female and her partner (if applicable). The potential impact of the relationship between the donor and recipient should be explored. The psychological assessment also should address the potential psychological risks and evaluate for evidence of coercion (financial or emotional). It is important to ascertain whether the donor is well informed about the extent to which information about him might be disclosed and about any plans that may exist relating to future contact.
5. No owner, operator, laboratory director, or employee of a facility performing TDI may serve as a donor in that practice.
6. Neither the patient's physician nor the individual performing the actual insemination can be the sperm donor.

B. Screening and testing of donors
1. Semen testing
a. It is suggested that more than one sample be examined (each after a 2- to 5-day abstinence interval) before proceeding with a more extensive evaluation of the donor candidate.
b. The sample should be examined within 1 to 2 hours after ejaculation into a sterile container. The criteria used to judge the normality of the sample can vary among laboratories. There are no uniformly accepted standards, but, in general, the minimum criteria for normal semen quality can be applied (1).
2. Genetic evaluation
Genetic screening for heritable diseases should be performed in potential sperm donors. Testing for cystic fibrosis carrier status should be performed on all donors. Other genetic testing should be performed as indicated by the donor's ethnic

background in accordance with current recommendations after obtaining a proper family history. Chromosomal analyses on all sperm donors are not required (see Appendix A for further details regarding genetic screening and testing) (2–4).

3. Medical history
   a. Donors should be healthy and give no history to suggest hereditary disease.
   b. A complete personal and sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV, STIs, or other infections that might be transmissible via gamete donation. Prospective sperm donors with any of the following factors should not be accepted (for a complete list of screening questions, see "Uniform Donor Application" at www.sart.org):
      i. Men with a history of sex with another man in the preceding 5 years.
      ii. Men who have injected drugs for nonmedical reasons in the preceding 5 years, including intravenous, intramuscular, and subcutaneous injections.
      iii. Men with hemophilia or other related clotting disorders who have received human-derived clotting factor concentrates in the preceding 5 years.
      iv. Men who received clotting factors once to treat an acute bleeding event more than 12 months ago may be eligible to donate.
      v. Men who have had sex in exchange for money or drugs in the preceding 5 years.
      vi. Men who have had sex in the preceding 12 months with any person meeting any of the criteria described immediately above, or with any person having HIV infection, including a positive or reactive test to HIV virus, hepatitis B infection, or clinically active (symptomatic) hepatitis C infection.
      vii. Men who have been exposed within the last 12 months through percutaneous inoculation or contact with an open wound, nonintact skin, or mucous membrane to blood that is known or suspected to be infected with HIV, hepatitis B, and/or hepatitis C virus.
      viii. Men who have had close contact (e.g., living in the same household wherein sharing of kitchen and bathroom facilities occurs regularly) within 12 months preceding the donation with another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection.
      ix. Men who have been incarcerated in lockup, jail, or prison for more than 72 consecutive hours within the previous 12 months.
      x. Men who have had or have been treated for syphilis, gonorrhea, or chlamydia within the preceding 12 months. Deferral of donors is not necessary when there is evidence of successful treatment more than 12 months before.
      xi. Men who have undergone body piercing and/or tattooing procedures within the preceding 12 months in which sterile procedures were not used or it is unclear whether sterile procedures were used (e.g., contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used).
      xii. Men who have received a smallpox vaccination (vaccinia virus) for 21 days after vaccination or until the scab separates spontaneously and physical examination confirms the absence of a scab at the vaccination site (whichever is later). The donor should be deferred for 2 months if the scab was removed before spontaneous separation. If the donor experienced complications from vaccination, he should be deferred until 14 days after complete resolution of those complications. If the donor became infected as a result of close contact with a person recently vaccinated for vaccinia, he may be considered eligible for donation if the scab spontaneously separated, if 14 days have elapsed since resolution of all the vaccinia-related complications, or 3 months after the scab was otherwise removed.
      xiii. Men who have had a medical diagnosis or suspicion of West Nile virus (WNV) infection (based on symptoms and/or laboratory results or confirmed WNV viremia) should be deferred for 120 days after the onset of symptoms or diagnosis, whichever is later.
      xiv. Men who have tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT in the preceding 120 days.
      xv. Men who have been diagnosed with variant CJD (vCJD) or any other form of CJD.
      xvi. Men who have been diagnosed with dementia or any other degenerative or demyelinating disease of the central nervous system or other neurologic disease of unknown etiology. Potential donors who have a diagnosis of delirium (e.g., delirium caused by toxic/metabolic diseases or recent head trauma) would not be considered necessarily to have a diagnosis of dementia and should be evaluated by the medical director.

xvii. Men who are at increased risk for CJD. Donors are considered to have an increased risk for CJD if they have received a non-synthetic dura mater transplant, human pituitary-derived growth hormone, or have one or more blood relatives diagnosed with CJD.

xviii. Men who have a history of CJD in a blood relative unless: the diagnosis of CJD was subsequently found to be in error, the CJD was iatrogenic, or laboratory testing (gene sequencing) demonstrates that the donor does not have a mutation associated with familial CJD.

xix. Men who spent 3 months or more cumulatively in the United Kingdom (U.K.) from the beginning of 1980 through the end of 1996.

xx. Men who are current or former US military members, civilian military employees, or dependants of a military member or civilian employee who resided at US military bases in Northern Europe (Germany, Belgium, and the Netherlands) for 6 months or more cumulatively from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more cumulatively from 1980 through 1996.

xxi. Men who spent 5 years or more cumulatively in Europe from 1980 until present.

xxii. Men who received any transfusion of blood or blood components in the United Kingdom or France between 1980 and the present.

xxiii. Men or their sexual partners who were born or lived in certain countries in Africa (Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria) after 1977 (risk factor for HIV group O).

xxiv. Men who have received a blood transfusion or any medical treatment that involved blood in the countries listed in xxiii after 1977 (risk factor for HIV group O).

Note: Establishments using an HIV-1/2 antibody donor screening test that has been licensed by the FDA and is specifically labeled in the Intended Use section of the package insert as sensitive for the detection of HIV group O antibodies may delete items VI.B.3.b.xxiii and xxiv from their screening procedures. If screening questions VI.B.3.b.xxiii and xxiv also are asked, donor eligibility may be based on the donor test results, regardless of the answers to those two questions.

xxv. Men who have received xenotransplants (live cells, tissues, or organs from a nonhuman animal source or human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs) or have been in close contact with a xenotransplant recipient.

xxvi. Men who have received human organ or tissue transplants or treatment with human extracts.

4. Physical examination
   a. Before acceptance, and every 6 months while remaining an active donor, donors should undergo a complete physical examination and should be declined when any of the following findings are present (see www.sart.org Male Donor Physical Examination Form):
      i. Physical evidence for risk of sexually transmitted disease such as genital ulcerative lesions, herpes simplex, chancroid, or urethral discharge.
      ii. Physical evidence for risk of, or evidence of, syphilis.
      iii. Physical evidence of anal intercourse including perianal condylomata.
      iv. Physical evidence of non-medical percutaneous drug use such as needle tracks; the examination should include examination of tattoos, which might be covering needle tracks.
      v. Physical evidence of recent (within 12 months) tattooing, ear piercing, or body piercing where sterile technique was not used.
      vi. Disseminated lymphadenopathy.
      vii. Unexplained oral thrush.
      viii. Blue or purple spots consistent with Kaposi sarcoma.
      ix. Unexplained jaundice, hepatomegaly, or icterus.
      x. Large scab consistent with recent history of smallpox immunization.
      xi. Eczema vaccinatum, generalized vesicular rash, severely necrotic lesion (consistent with vaccinia necrosum), or corneal scarring (consistent with vaccinial keratitis).
5. Laboratory testing

   There is no method to ensure completely that infectious agents will not be transmitted by TDI. However, the following guidelines, combined with an adequate history and specific exclusion of individuals at high risk for HIV and other STIs, should significantly reduce these risks. The FDA requires that the following tests be performed, using methods required for purposes of determining donor eligibility, and that negative results are documented before use of the donor's sperm. The list of test methods approved by the FDA for this purpose is available at the following Web sites:

   http://www.fda.gov/cber/products/testkits.htm

http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf

Clinics using donor sperm from a commercial sperm bank should have documentation from the bank that they adhere to federal and local requirements (5).

a. HIV-1 antibody as well as NAT.
b. HIV-2 antibody.
c. HIV group O antibody. Establishments that do not use an FDA-licensed test for HIV group O antibodies must evaluate donors for risk associated with HIV group O infection with additional screening questions as described in VI.B.3.b.x-xiii and xxiv.
d. Hepatitis C antibody and NAT.
e. Hepatitis B surface antigen.
f. Hepatitis B core antibody (IgG and IgM).
g. Serologic test for syphilis.
h. HTLV-1 and HTLV-2.
i. CMV (IgG and IgM). Men who test positive for active infection (positive urine or throat culture or paired serum samples demonstrating a four-fold rise in IgG antibody and IgM antibody at least 30% of the IgG level) should be excluded. Because CMV is so common, insemination with semen from a CMV-seropositive man (without active infection) is permissible when the female partner is also CMV seropositive. Although the practice is not entirely without risk, because there are many strains of CMV and superinfection is possible, the associated risk of newborn CMV infection is approximately 1%, and such infants appear to have no significant illness or other abnormality.
j. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the urethral meatus. These tests should be repeated if clinically indicated. Retesting of the donor at 6-month intervals is required as long as the donor remains active.

   N.B. There are no FDA-licensed, approved or cleared tests for donor screening of these organisms in an asymptomatic, low-prevalence population. Tests using NAT technology adequately and appropriately reduce the risk of transmission of these relevant communicable agents.
k. Donors found to be positive for syphilis, *Neisseria gonorrhoeae*, or *Chlamydia trachomatis* should be treated, retested, and deferred from donation for 12 months after documentation that treatment was successful before being reconsidered. If evidence is presented that treatment occurred more than 12 months ago and was successful, no further deferral is needed as long as current testing does not indicate an active infection.
l. Abbreviated donor screening documenting no change in the donor's medical and/or social history should be performed at 6-month intervals.
m. Additional testing should be performed as dictated by local or state requirements.
n. Additional testing not required by the FDA but recommended by the ASRM includes blood type and Rh. If the use of donor oocytes creates the potential for Rh incompatibility, couples should be informed about obstetric significance of this condition.

6. Managing laboratory results
   a. If testing is negative, semen samples may be collected and prepared for cryopreservation.
   b. A positive test should be verified before notifying the potential donor. If a test is confirmed positive, the individual should be referred for appropriate counseling and management.
   c. Individuals who initially test positive (except for treated syphilis, *Neisseria gonorrhoeae*, or *Chlamydia trachomatis* as described earlier) are not eligible for anonymous donation.
   d. False-positive results for syphilis using non-treponemal assays that are confirmed to be negative using a treponemal-based assay are eligible for donation.
   e. After donation, anonymous donor specimens must be quarantined for a minimum of 180 days. The donor must be retested (see section VI.B.5) after the required quarantine interval, and specimens may be released only if the results of repeat testing are negative.
   f. Screening and testing of donors for STIs and genetic risk factors may change over time as tests improve and new tests become available. Therefore, samples of sperm that are cryopreserved and stored for periods of time may not meet existing testing standards at the time they are released for use. In such instances, every effort should be made to have the donor tested in accordance with current standards. In situations where the donor is not available or refuses such additional testing, the sample(s) may be released provided that the recipient is informed that the specimen does not meet current screening and testing guidelines, is informed of what tests have not been performed, and is counseled regarding the clinical implications of the missing information.
7. Directed donation

   Directed (non-anonymous or known) donation is acceptable if all parties agree. Directed donors must undergo the same screening and testing as anonymous donors. Directed donors who test positive or demonstrate a risk factor for a relevant communicable disease are not prohibited from use according to current FDA rules, provided that the tissue is labeled to indicate any associated increased

risks and that physicians using samples are aware of the status of the results. Although the FDA does not require informing the recipients of the test results, in the opinion of the ASRM the recipients must be informed and counseled appropriately before use of the samples. Directed donor specimens also are exempt from quarantine under the current FDA guidelines, which require only retesting as described earlier (see section VI.B.5) within 7 days before donation. However, in the opinion of the ASRM, directed donor specimens should be treated in the same manner as anonymous donor specimens; results of testing that would exclude an anonymous donor also should exclude a directed donor, and directed donor specimens should be quarantined and released in the same manner required for anonymous donor specimens (see sections VI.B.1–6).

8. Use of fresh semen
   In the opinion of the ASRM, the use of fresh semen can be justified only for sexually intimate couples. It is possible for HIV and other infectious organisms to be transmitted by fresh donor semen before the donor has become seropositive. Consequently, the potential for transmission of infections by fresh semen cannot be eliminated. The ASRM recommends that all directed donor specimens be frozen and quarantined for a minimum of 180 days, with the donor then retested as described above (see section VI.B.5) and demonstrated seronegative before the specimen is released.

C. Management of donors
   1. Monitoring health status
      The single most important method for reducing the risk of transmitting infectious agents to women during insemination is to screen carefully and test the potential donors and to develop an ongoing procedure for monitoring their health status.
   2. Payment to donors
      Payment to donors varies from area to area but should not be such that the monetary incentive is the primary motivation for donating sperm. However, the donor may be compensated for his time and expenses.
   3. Limitations to donor use
      Institutions, clinics, and sperm banks should maintain sufficient records to allow a limit to be set for the number of pregnancies for which a given donor is responsible. It is difficult to provide a precise number of times that a given donor can be used because one must take into consideration the population base from which the donor is selected and the geographic area that may be served by a given donor. It has been suggested that in a population of 800,000, limiting a single donor to no more than 25 births would avoid any significant increased risk of inadvertent consanguineous conception. This suggestion may require modification if the population using donor insemination represents an isolated subgroup or if the specimens are distributed over a wide geographic area.
   4. Consent
      It is essential for the donor to sign a consent form, which should include a firm denial of having any recognized risk factors for STIs and genetic diseases. It is recommended that the donor acknowledge in the consent form his responsibility to notify the donor program of any changes in his health or risk factor status.
   5. Record keeping
      The FDA requires that records pertaining to each donor (screening and test results) be maintained for at least 10 years. However, in the opinion of the ASRM, a permanent record of each donor's initial selection process and subsequent follow-up evaluations should be maintained. Ideally, the clinical outcome of each insemination cycle should be recorded as well as a mechanism for reporting any adverse outcomes including heritable diseases identified preconceptually or post natally. In the event that a previously unidentified heritable disease is encountered in a child produced from anonymous donation, the donor as well as the recipient of the donated sperm should be tested and further release of samples from the donor should be prohibited. If the donor is found to be the carrier for the heritable disease, all recipients of that donated sperm as well as the clinics performing the procedures should be notified and counseled. A mechanism must exist to maintain records on the donor as a future medical resource for any offspring produced.
   6. Protection of confidentiality
      Individuals participating in donor programs should be assured that their confidentiality will be protected insofar as federal and local statutes permit. Medical records detailing the donation should be maintained as stipulated by federal and local requirements.

VII. Choosing donor characteristics
   There are several methods for matching the male partner with the donor. The couple should be encouraged to list the characteristics that they desire in a prospective donor, including race and/or ethnic group, height, body build, complexion, eye color, and hair color and texture. Consideration should be given to blood type and Rh factor, particularly for Rh-negative recipients. If the use of donor sperm creates the potential for Rh incompatibility, recipients should be informed of the obstetric implications of the condition.

GUIDELINES FOR OOCYTE DONATION

I. Introduction
   Oocyte donation requires ovarian stimulation with monitoring and oocyte retrieval, involving significant inconvenience, discomfort, and risks for the donor.

II. Indications for use of donor oocytes
   A. Women with hypergonadotropic hypogonadism.
   B. Women of advanced reproductive age.

C. Women who have diminished ovarian reserve.
D. Women who are known to be affected by or known to be the carrier of a significant genetic defect or who have a family history of a condition for which carrier status cannot be determined.
E. Women with poor oocyte and/or embryo quality or multiple previous failed attempts to conceive via ART.

III. Psychological consultation for oocyte donor recipients
The decision to proceed with donated oocytes is complex, and patients and their partners (if applicable) may benefit from psychological counseling to aid in this decision. The clinician should strongly recommend psychological counseling by a qualified mental health professional to all donor oocyte recipients and their partners. The assessment should include a clinical interview and, where appropriate, psychological testing. The clinician should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation. In cases of directed donation, the potential impact of the relationship between the donor and recipient should be explored, as well as any plans that may exist relating to disclosure and future contact.

IV. Evaluation of the oocyte recipient
A. Medical and reproductive history
1. Routine medical and reproductive histories should be obtained according to the standards that are applied to women anticipating pregnancy. Reproductive abnormalities detected from history or physical examination may require more detailed evaluation and treatment before donor oocytes are used.
B. A complete general physical examination should be performed, including a pelvic examination.
C. Assessment of the uterine cavity
1. HSG, saline infusion ultrasonography, or another suitable procedure should be performed to detect any significant uterine abnormality.
D. Standard preconceptional testing and counseling
1. Although there are no federal requirements for testing oocyte recipients, the following tests are recommended:
a. Blood type, Rh factor, and antibody screen.
b. Rubella and varicella titers. Recipients should be offered immunization if not immune.
c. HIV-1 (AB and NAT), HIV-2 AB testing and screening or testing for HIV group O antibodies. HIV testing should be performed to address potential medical/legal complications that could arise if the recipient seroconverts during or after treatment. In addition, if the female recipient is found to be HIV infected before treatment, she should be referred to an appropriate infectious disease specialist for counseling on issues concerning HIV disease, including reproductive issues such as safe sex practices for preventing HIV transmission to uninfected partners and treatment options to reduce the probability of transmission to her child; counseling should be documented in the medical record. A positive HIV test of the female recipient should not be used as an exclusionary criterion for treatment, provided that the couple makes an informed decision after counseling and agrees to comply with recommended clinical management for the positive HIV state.
d. Serologic test for syphilis.
e. Hepatitis B surface antigen.
f. Hepatitis B core antibody (IgG and IgM).
g. Hepatitis C antibody and NAT.
h. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the cervix, urethral meatus, or vagina.

V. Evaluation of the partner of the oocyte recipient
A. Laboratory tests. Although there are no federal requirements for testing the partner of the oocyte recipient, the following tests are recommended:
1. Semen analysis for male partners.
2. Blood type and Rh factor.
3. Serologic test for syphilis.
4. Hepatitis B surface antigen.
5. Hepatitis B core antibody (IgG and IgM).
6. Hepatitis C antibody and NAT.
7. HIV-1 (AB and NAT), HIV-2 AB testing and screening, or testing for HIV group O antibodies. HIV testing should be performed to address potential medical/legal complications that could arise if the recipient seroconverts during or after treatment. In addition, if the partner is found to be HIV infected before treatment, he should be referred to an appropriate infectious disease specialist for counseling on issues concerning HIV disease, including reproductive issues such as safe sex practices for preventing HIV transmission to uninfected partners. Counseling should be documented in the medical record. A positive HIV test of the partner should not be used as an exclusionary criterion for treatment.
8. Appropriate genetic screening and testing based on history, in accordance with ethnic background and current recommendations (see Appendix A) (2–4).

VI. Donors
A. Selection of donors
1. Oocyte donation may be undertaken with known or anonymous donors depending on the clinical circumstances.
2. Psychological evaluation and counseling by a qualified mental health professional is strongly recommended for the oocyte donor and her partner (if applicable). The assessment should include a clinical interview and, where appropriate, psychological testing. Psychological consultation should be required for individuals in whom there appear to be factors that warrant further evaluation. In circumstances involving known donors, psychological evaluation and counseling is strongly recommended for the donor and her partner, if applicable, as well as for the recipient and her partner, if applicable. The potential impact of the

relationship between the donor and recipient should be explored. The psychological assessment also should address the potential psychological risks and evaluate for evidence of coercion (financial or emotional). It is important to ascertain whether the donor is well informed about the extent to which information about her may be disclosed and about any plans that may exist relating to future contact.

3. Oocyte donors should be of legal age and preferably between the ages of 21 and 34 years.
4. Donors less than 21 years of age should have psychological evaluation by a qualified mental health professional, and the decision to proceed with such a donor should be determined on an individual basis.
5. If a prospective donor is over 34 years of age, the age of the donor should be revealed to the recipient as part of the informed consent discussion concerning cytogenetic risks and the effect of donor age on pregnancy rates.
6. Proven fertility in the donor is desirable but not required.
7. The donor should undergo appropriate genetic evaluation based on history, in accordance with ethnic background and current guidelines. Cystic fibrosis testing should be performed on all donors. Consideration should be given to fragile X testing on donors, but is not required (see Appendix A) (2–4).
8. Sharing of oocytes from an assisted reproduction cycle: If sharing of oocytes is contemplated, informed consent must be obtained before the start of the cycle of retrieval. The conditions governing the sharing of oocytes should be specified in advance, be included in the informed consent, and comply with existing ASRM Ethics Committee guidelines (6).
9. No owner, operator, laboratory director, or employee of a facility screening for or performing oocyte donation may serve as a donor in that practice.
10. If an agency is used to recruit oocyte donors, no individual who has a financial interest in that agency may be used as an oocyte donor.

B. Screening and testing of oocyte donors

1. Donors should be healthy and give no history to suggest hereditary disease.
2. A complete personal and sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV, STIs, or other infections that might be transmissible via gamete donation. Prospective oocyte donors with any of the following factors should not be accepted (for a complete list of screening questions, see "Uniform Donor Application" at www.sart.org):
   a. Women who have injected drugs for non-medical reasons in the preceding 5 years, including intravenous, intramuscular, and subcutaneous injections.
   b. Women with hemophilia or other related clotting disorders who have received human-derived clotting factor concentrates in the preceding 5 years.
      i. Women who received clotting factors to treat an acute bleeding event more than 12 months prior to planned donation may be eligible to donate.
   c. Women who have had sex with a man who has had sex with another man in the past 5 years.
   d. Women who have had sex in exchange for money or drugs in the preceding 5 years.
   e. Women who have had sex in the preceding 12 months with any person meeting any of the criteria described immediately above, or with any person having HIV infection including a positive or reactive test to HIV virus, hepatitis B infection, or clinically active (symptomatic) hepatitis C infection.
   f. Women who have been exposed within the last 12 months, through percutaneous inoculation or contact with an open wound, non-intact skin, or mucous membrane, to blood that is known or suspected to be infected with HIV, hepatitis B, and/or hepatitis C virus.
   g. Women who have had close contact (e.g., living in the same household wherein sharing of kitchen and bathroom facilities occurs regularly) within 12 months preceding the donation with another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection.
   h. Women who have been incarcerated in lock-up, jail, or prison for more than 72 consecutive hours within the previous 12 months.
   i. Women who have had or have been treated for syphilis, gonorrhea, or chlamydia within the preceding 12 months. Deferral of donors is not necessary if evidence is presented that treatment occurred more than 12 months ago and was successful.
   j. Women who have undergone body piercing and/or tattooing procedures within the preceding 12 months in which sterile procedures were not used or it is unclear whether sterile procedures were used (e.g., contaminated instruments and/or ink were used or shared instruments that had not been sterilized between uses were used).
   k. Women who have received a smallpox vaccination (vaccinia virus) for 21 days after vaccination or until the scab separates spontaneously and physical examination confirms the absence of a scab at the vaccination site (whichever is later). The donor should be deferred for 2 months if the scab was removed before spontaneous separation. If the donor experienced complications from vaccination, she should be deferred until 14 days after complete resolution of those complications. If the donor became infected as

a result of close contact with a person recently vaccinated for vaccinia, she may be considered eligible for donation if the scab spontaneously separated, if 14 days have elapsed since resolution of all the vaccinia-related complications, or 3 months after the scab was otherwise removed.

l. Women who have had a medical diagnosis or suspicion of WNV infection (based on symptoms and/or laboratory results or confirmed WNV viremia) should be deferred for 120 days after the onset of symptoms or diagnosis, whichever is later.
m. Women who have tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT donor-screening test in the preceding 120 days.
n. Women who have been diagnosed with vCJD or any other form of CJD.
o. Women who have been diagnosed with dementia or any other degenerative or demyelinating disease of the central nervous system or other neurologic disease of unknown etiology. Potential donors who have a diagnosis of delirium (e.g., delirium caused by toxic/metabolic diseases or recent head trauma) would not be considered necessarily to have a diagnosis of dementia and should be evaluated by the medical director.
p. Women who are at increased risk for CJD. Donors are considered to have an increased risk for CJD if they have received a non-synthetic dura mater transplant, human pituitary-derived growth hormone, or have one or more blood relatives diagnosed with CJD.
q. Women who have a history of CJD in a blood relative unless the diagnosis of CJD was subsequently found to be in error, the CJD was iatrogenic, or laboratory testing (gene sequencing) demonstrates that the donor does not have a mutation associated with familial CJD.
r. Women who spent 3 months or more cumulatively in the United Kingdom from the beginning of 1980 through the end of 1996.
s. Women who are current or former US military members, civilian military employees, or dependants of a military member or civilian employee who resided at US military bases in Northern Europe (Germany, Belgium, and the Netherlands) for 6 months or more cumulatively from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more cumulatively from 1980 through 1996.
t. Women who spent 5 years or more cumulatively in Europe from 1980 until present.
u. Women who received any transfusion of blood or blood components in the United Kingdom or France between 1980 and the present.
v. Women or their sexual partners who were born or lived in certain countries in Africa (Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria) after 1977 (risk factor for HIV group O).
w. Women who have received a blood transfusion or any medical treatment that involved blood in the countries listed above after 1977 (risk factor for HIV group O).

Note: Establishments using an HIV-1/2 antibody donor screening test that has been licensed by the FDA and is specifically labeled in the Intended Use Section of the package insert as sensitive for the detection of HIV group O antibodies may delete items VI.B.2.v and VI.B.2.w from their screening procedures. If screening questions VI.B.2.v and VI.B.2.w also are asked, donor eligibility may be based on the results of the donor test results regardless of the answers to those two questions.

x. Women who have received xenotransplants (live cells, tissues, or organs from a nonhuman animal source or human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs) or have been in close contact with a xenotransplant recipient.
y. Women who have received human organ or tissue transplants or treatment with human extracts.

3. Before acceptance, and every 6 months while remaining an active donor, donors should undergo a complete physical examination and should be declined when any of the following findings are present (see female donor physical exam at www.sart.org):
   a. Physical evidence for risk of sexually transmitted disease such as genital ulcerative lesions, herpes simplex, chancroid, and urethral discharge.
   b. Physical evidence for risk of or evidence of syphilis.
   c. Physical evidence of anal intercourse including perianal condylomata.
   d. Physical evidence of non-medical percutaneous drug use such as needle tracks; the examination should include examination of tattoos, which might be covering needle tracks.
   e. Physical evidence of recent (within 12 months) tattooing, ear piercing, or body piercing where sterile procedure was not used.
   f. Disseminated lymphadenopathy.
   g. Unexplained oral thrush.
   h. Blue or purple spots consistent with Kaposi sarcoma.
   i. Unexplained jaundice, hepatomegaly, or icterus.
   j. Large scab consistent with recent history of smallpox immunization.
   k. Eczema vaccinatum, generalized vesicular rash, severely necrotic lesion (consistent with vaccinia necrosum), or corneal scarring (consistent with vaccinial keratitis).
4. Laboratory testing

   There is no method to ensure completely that infectious agents will not be transmitted via oocyte donation. However, the following guidelines, combined

with an adequate medical history and specific exclusion of individuals at high risk for HIV and other STIs, should dramatically reduce these risks. The FDA requires that the following tests be performed within 30 days of oocyte collection, using methods required for purposes of determining donor eligibility, and that negative results are documented before use of the donor's oocytes. The list of test methods approved by the FDA for this purpose is available at the following Websites:

http://www.fda.gov/cber/products/testkits.htm

http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf

a. HIV-1 antibody as well as NAT.
b. HIV-2 antibody.
c. HIV group O antibody. Establishments that do not use an FDA-licensed test for group O antibodies must evaluate donors for risk associated with HIV group O infection as described in VI.B.2.v and w.
d. Hepatitis C antibody and NAT.
e. Hepatitis B surface antigen.
f. Hepatitis B core antibody (IgG and IgM).
g. Serologic test for syphilis.
h. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the cervix, urethral meatus, or vagina.
i. Although not required by the FDA, recommended tests also include blood type and Rh factor. If the use of donor oocytes creates the potential for Rh incompatibility, couples should be informed about the obstetric significance of this condition.

C. Managing laboratory results
1. A positive test should be verified before notifying the potential donor. If a test is confirmed positive, the individual should be referred for appropriate counseling and management.
2. Individuals who initially test positive (except for treated syphilis, *Neisseria gonorrhoeae*, or *Chlamydia trachomatis* as described above) are not eligible for anonymous donation.
3. False positive results for syphilis using nontreponemal assays that are confirmed to be negative using a treponemal-based assay are eligible for donation.
4. Donors found to be positive for syphilis, *Neisseria gonorrhoeae*, or *Chlamydia trachomatis* should be treated, retested, and deferred from donation for 12 months after documentation that treatment was successful before being reconsidered. If evidence is presented that treatment occurred more than 12 months ago and was successful, no further deferral is needed as long as current testing does not indicate an active infection.

D. Quarantining of oocytes
At this time, oocyte freezing cannot be performed reliably; therefore, the quarantining of oocytes is not practical. All potential recipient couples should be offered the option of cryopreserving and quarantining embryos derived from donor oocytes for 180 days, with release of embryos only after the donor has been retested with confirmed negative results (see section VI.B.4). However, couples also should be informed that embryo cryopreservation may significantly reduce implantation rates. The recipient couple should be counseled appropriately in the event of seroconversion of the oocyte donor after cryopreservation of the embryos or if the donor refuses to be retested.

E. Directed donation
Directed (non-anonymous or known) donation is acceptable if all parties agree. Directed donors must undergo the same screening and testing as anonymous donors. Directed donors who test positive or demonstrate a risk factor for a relevant communicable disease are not prohibited from use according to current FDA rules, provided that the tissue is labeled to indicate any associated increased risks and that physicians using samples are aware of the status of the results. Although the FDA does not require informing the recipients of the test results, the ASRM recommends that the recipients must be informed and counseled appropriately before use of the samples. Additionally, the ASRM recommends that directed-donor specimens should be treated in the same manner as anonymous-donor specimens; results of testing that would exclude an anonymous donor also should exclude a directed donor.

F. Payment to the donor
1. Compensation to the donor should be in compliance with the ASRM Ethics Committee report on the subject (7).
2. Monetary compensation of the donor should reflect the time, inconvenience, and physical and emotional demands and risks associated with oocyte donation and should be at a level that minimizes the possibility of undue inducement of donors and the suggestion that payment is for the oocytes themselves.
3. Financial obligations and responsibilities in the event of complications or medical expenses of a donor should be agreed upon contractually before initiation of a stimulation cycle.
4. Payment may be prorated based on the number of steps completed in the procedure.
5. Payment should not be predicated on clinical outcome.

G. Multiple oocyte donations
This subject is addressed specifically in the ASRM Practice Committee Opinion entitled "Repetitive Oocyte Donation" (8).

H. Unintended donor pregnancies
The donor should be counseled about the possibility of unintended pregnancy and offered options for prevention.

I. Age of the recipient
In view of the concerns about pregnancy in women of advanced reproductive age, it is recommended that potential recipients over the age of 45 undergo thorough medical evaluation (including cardiovascular testing) and a high-risk obstetric consultation before undertaking IVF with donor oocytes.

J. Record keeping
The FDA requires that records pertaining to each donor (screening and test results) be maintained for at least 10 years. However, in the opinion of the ASRM, a permanent record of each donor's initial selection process and subsequent follow-up evaluations should be maintained. Ideally, the clinical outcome for each donation cycle should be recorded as well as a mechanism for reporting any adverse outcomes including heritable diseases identified preconceptually or post natally. In the event that a previously unidentified heritable disease is encountered in a child produced from anonymous donation, the donor as well as the recipient of the donated oocytes should be tested and the donor should be prohibited from further donation until the results of such testing are known. If the donor is found to be the carrier for the heritable disease, all women who received oocytes from that donor as well as the clinics performing the procedures should be notified and counseled. A mechanism must exist to maintain records on the donor as a future medical resource for any offspring produced.

K. Legal issues and informed consent
1. All oocyte donors should be advised explicitly of the risks and adverse effects of ovarian stimulation and retrieval, with such counseling documented by informed consent in the patient's permanent medical record.
2. Donors and recipients and their partners, if applicable, should execute documents that define or limit their rights and duties with regard to any offspring.
3. Couples and donors who have legal concerns not addressed in the informed-consent process should be advised to seek legal consultation.
4. Protection of confidentiality: Individuals participating in donor programs should be assured that their confidentiality will be protected insofar as federal and local statutes permit. Medical records detailing the donation should be maintained as stipulated by local requirements.
5. It is recommended that the donor acknowledge in the consent form her responsibility to notify the donor program of any changes in her health or risk-factor status.

GUIDELINES FOR CRYOPRESERVED EMBRYO DONATION

Background

In the current clinical practice of ART, more embryos than can be transferred safely at one time commonly are generated. In the majority of ART practices, these embryos may be cryopreserved for later transfer. Couples who become pregnant and do not desire another pregnancy, or have other reasons for choosing not to use their embryos, may have the option of discarding these embryos or donating them to other individuals or to research. It is the purpose of this document to present guidelines for embryo donation. It should be noted that these guidelines represent minimum standards for screening, testing, and counseling of potential embryo donors and recipients. The federal government has published minimum requirements for embryo donation (6). Some states and other localities may have laws or regulations that pertain to embryo donation that may supersede these guidelines.

I. Guidelines for ART practices that offer embryo donation
A. The practice should be knowledgeable in the storage, thawing, and transfer of frozen embryos.
B. The practice may charge a professional fee to the potential recipients for embryo thawing, the embryo transfer procedure, cycle coordination and documentation, and infectious disease screening and testing of both recipients and donors. However, the selling of embryos per se is ethically unacceptable.
C. It is acceptable for a practice or cryostorage facility to have conservatorship of embryos given up for potential embryo donation by patients whose gametes were used to generate the embryos.
D. Embryos should be quarantined for a minimum of 6 months before the potential donors are screened and tested or retested as noted in section II, with documentation of negative results.
E. Physicians and employees of an infertility practice should be excluded from participating in embryo donation as either donors or recipients within that practice.

II. Embryo donation
Eligibility of donors is determined by the gametes, not the embryos being donated. For embryos derived from gametes obtained from an anonymous donor or donors, the donor or donors must have met all FDA screening and testing requirements and must have been determined eligible for anonymous donation as described above for anonymous sperm and/or oocyte donation. If one or both of the donors is known to the recipient, gametes that were determined to be ineligible still can be used and those embryos are not prohibited from use according to current FDA rules, provided that the tissue is labeled to indicate any associated increased risks and that physicians using samples are aware of the status of the results. Although the FDA does not require informing the recipients of the test results, the ASRM recommends that the recipients be informed and counseled appropriately before transfer of the embryos.
Embryos derived from the gametes of a sexually intimate couple and created for use by that couple are exempt from the requirements for donor screening and testing before creation of the embryos. The following guidelines apply to sexually intimate couples who decide to donate unused embryos that are the product of their own biological gametes:

A. Embryo donors must provide a medical and genetic history.
B. The gamete donors used to create the embryos should be screened for relevant risk factors for HIV, other transmissible infections, and TSE (9).
C. There is no method to ensure completely that infectious agents will not be transmitted, but the following guidelines, combined with an adequate medical history and specific exclusion of individuals at high risk for HIV and other transmissible infections, should dramatically reduce these risks. The practice should determine if the cost of such tests will be borne by the donor couple, by the practice mediating the embryo donation, or by the potential recipients. The following recommended tests should be performed using methods approved by the FDA for use in determining donor eligibility, on both partners, before gamete collection and more than 180 days after cryopreservation of the embryos to be donated.
    1. HIV-1 antibody and NAT.
    2. HIV-2 antibody.
    3. HIV group O antibody. Establishments that do not use an FDA-licensed test for group O antibodies should evaluate donors for risk associated with HIV group O infection (see screening questionnaires for anonymous sperm and oocyte donation).
    4. Hepatitis B surface antigen.
    5. Hepatitis B core antibody (IgG and IgM).
    6. Hepatitis C antibody and NAT.
    7. Serologic test for syphilis.
    8. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT.
    9. Although not required by the FDA, recommended tests also include:
        a. Blood type and Rh factor.
    10. In addition, the male gamete donor should be tested for:
        a. HTLV-1 and HTLV-2.
        b. CMV (IgG and IgM) antibody.
    11. If not already performed, appropriate genetic evaluation and testing should be conducted.
D. Often, screening and testing of the biological source of the gametes used to create the embryos in sexually intimate partners was not done, and the decision to donate embryos occurred subsequent to their creation. If the decision to donate is made more than 180 days after cryopreservation of the embryos, the donors may be rescreened and tested. In this instance, the documentation that accompanies the embryos must include the following label: "Advise recipient that screening and testing of the donors were not performed at the time of cryopreservation of the reproductive cells or tissue but have been performed subsequently."
E. If the donors are not available or refuse to undergo the required screening and testing, FDA guidelines do not preclude the use of their embryos, provided that the documentation that accompanies the embryos includes the following labels: "NOT EVALUATED FOR INFECTIOUS SUBSTANCES," and "WARNING: Advise recipient of communicable disease risks." However, the ASRM recommends careful counseling regarding the risks of transfer of these embryos.
F. Embryos that are shipped to another facility must be accompanied by a summary of records and must be appropriately labeled, in accordance with FDA guidelines. The receiving facility should not accept embryos that are not accompanied by a summary of records or that are not appropriately labeled (10).
G. The embryo donors must sign an informed-consent document indicating their permission to use their embryos for embryo donation. Issues to be addressed in the consent form include:
    1. Relinquishing all rights of the donor(s) to the embryo(s) and any child or children that may result from the transfer of such embryo(s).
    2. Inadvertent loss or damage to the embryo(s).
    3. The right of the practice to refuse transfer to an inappropriate recipient.
    4. The length of time that donated embryos will be maintained in cryostorage, and the alternatives for their disposition thereafter.
    5. Jurisdiction and process for medical/legal procedures and/or dispute resolution.
H. Proper chain-of-custody procedures must be followed and documented for the handling of all test specimens and for donated embryos.
I. Donors should receive no compensation for the embryos.
J. The decision to proceed with embryo donation is complex, and patients may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all couples considering donating embryos. The assessment should include a clinical interview and, where appropriate, psychological testing. The clinician should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation. In circumstances involving known donors, psychological evaluation and counseling is strongly recommended for the donor and partner, if applicable, as well as for the recipient and her partner, if applicable. The potential impact of the relationship between the donor and recipient should be explored. It is important to ascertain whether the donor is well informed about the extent to which information about her may be disclosed and about any plans that may exist relating to future contact.
K. Donors should be advised that additional testing may be necessary prior to releasing embryos for donation.

III. Guidelines for potential recipients
A. The recipient(s) must take full responsibility for the embryo(s) and any child or children that may result from the transfer.
B. The recipient(s) must release the gamete donors from any and all liability from any potential complications of the pregnancies, congenital abnormalities, heritable

diseases, or other complications of the embryo donation. The ART program should also be absolved of liability from potential complications of pregnancy, congenital abnormalities, and heritable diseases.

C. The ASRM recommends that the recipient(s) submit to the same blood tests for infectious disease testing as the donors (V.C.1.a-j under Guidelines for Sperm Donation).

D. Although not required by the FDA, recommended tests also include blood type and Rh factor. If the use of donor embryos creates the potential for Rh incompatibility, couples should be informed about the obstetric significance of this condition.

E. The decision to proceed with embryo donation is complex, and patients may benefit from psychological counseling to aid in this decision. Psychological consultation with a qualified mental health professional is strongly recommended for all individuals receiving donated embryos. The assessment should include a clinical interview and, where appropriate, psychological testing. The physician should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation. In circumstances involving known donors, psychological evaluation and counseling is strongly recommended for the recipient and her partner, if applicable. The potential impact of the relationship between the donor and recipient should be explored. It is important to ascertain whether the recipient is well informed about any plans that may exist relating to future contact.

IV. Record keeping

The FDA requires that records pertaining to each donor (screening and test results) be maintained for at least 10 years. However, in the opinion of the ASRM, a permanent record of each donor's screening and test results should be maintained. To the extent possible, the clinical outcome should be recorded for each donation cycle. A mechanism must exist to maintain such records as a future medical resource for any offspring produced.

V. Protection of confidentiality

Individuals participating in donor programs should be assured that their confidentiality will be protected insofar as federal and local statutes permit. Medical records detailing the donation should be maintained as stipulated by local requirements.

PSYCHOLOGICAL ASSESSMENT OF GAMETE DONORS AND RECIPIENTS

Statement of Purpose

The following recommendations are intended to provide general guidelines for addressing the many complex moral, ethical, and psychosocial issues that confront gamete donors, recipients, and offspring.

I. Donors

A. The decision to proceed with gamete donation is complex, and individuals may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all individuals considering gamete donation. The assessment should include a clinical interview and, where appropriate, psychological testing. The physician should require psychological consultation for donors in whom there appear to be factors that warrant further evaluation.

1. If indicated, psychological testing should document and validate in a standardized objective manner the information gathered from the clinical interview and should include an objective personality test and other self-report measures to assess potential instability or psychopathology.

B. A psychosocial history should include:

1. Family history.
2. Educational background.
3. Assessment of stability.
4. Motivation to donate.
5. Current life stressors and coping skills.
6. Difficult or traumatic reproductive history.
7. Interpersonal relationships.
8. Sexual history.
9. Travel history.
10. History of major psychiatric and personality disorders.
11. Substance abuse in donor or first-degree relatives.
12. Legal history.
13. History of abuse or neglect.

C. The psychological assessment should ensure that the donor has been informed about all relevant aspects of the medical treatment. Donors should be counseled about the number and type of infectious disease tests that will be performed and informed about how that information will be used and shared with others.

D. The psychological assessment also should address the potential psychological risks and should evaluate for evidence of coercion (financial or emotional). It also is important to ascertain whether the donor is well informed about the extent to which information about him/her might be disclosed and about any plans that may exist relating to future contact. The donor must be aware of all aspects of potential embryo management and disposition applicable to that practice. Donors should be informed about how the information will be used, stored, and secured.

E. Relative exclusion criteria for a gamete donor include:

1. Presence of significant psychopathology.
2. Positive family history of heritable psychiatric disorders.
3. Substance abuse.
4. Two or more first-degree relatives with substance abuse.
5. Current use of psychoactive medications.
6. History of sexual or physical abuse with no professional treatment.
7. Excessive stress.
8. Marital instability.
9. Impaired cognitive functioning.
10. Mental incompetence.

11. High-risk sexual practices.

F. Candidates who are excluded from the donor practice should be counseled regarding the reasons for their exclusion and, if appropriate, offered referral.

G. In cases involving known donors, related issues such as the potential impact of the relationship between the donor and recipient should be explored. The impact on treatment failure also should be addressed.

II. Recipients

A. The decision to proceed with gamete donation is complex, and patients may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all patients considering gamete donation. The assessment should include a clinical interview and, where appropriate, psychological testing. The physician should require psychological consultation for patients in whom there appear to be factors that warrant further evaluation.

B. The recipient should be counseled about his/her subsequent feelings concerning the medical conditions that necessitated the use of donor gametes.

C. Counseling should address the impact of successful treatment: feelings during pregnancy, positive and negative aspects of disclosure and nondisclosure with offspring, potential impact of multiple pregnancy, transition to parenthood, parenting at an older age (if applicable), and nonbiological parenting issues.

D. The impact of treatment failure also should be addressed: coping with treatment termination, the grieving process, and developing alternatives for the future.

E. In cases involving known donors, related issues, such as the potential impact of the relationship between donor and recipient, should be explored.

F. The recipients should be informed about the screening and testing required of the donor. The couple should be made aware that a donor may be deemed unsuitable for donation and that the practice may refuse to use these gametes for treatment. If the recipient couple elects to use a donor who is deemed unsuitable, then additional counseling must involve risk management and an agreement that the recipient couple understands and assumes the risk. Couples should be informed that the records related to the screening and testing of the donor will be stored. The storage of this information is relevant to the recipients because it relates to other information-sharing decisions they may make.

PSYCHOLOGICAL GUIDELINES FOR EMBRYO DONATION

Statement of Purpose

The following recommendations are intended to provide general guidelines for addressing the many complex moral, ethical, and psychosocial issues that confront embryo donors, recipients, and offspring.

I. Donors

A. All potential donor couples should be informed about all aspects of their medical treatments and the relevant psychological and ethical issues inherent in donating embryos.

B. There should be a discussion of embryo disposition options before cryopreservation. After couples have concluded their own reproductive attempts, embryo disposition options should be re-evaluated.

C. The decision to proceed with embryo donation is complex, and patients may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all patients considering donating embryo(s). The assessment should include a clinical interview and, where appropriate, psychological testing. The clinician should require psychological consultation for patients in whom there appear to be factors that warrant further evaluation. In circumstances involving known donors, psychological evaluation and counseling is strongly recommended for the donors. The potential impact of the relationship between the donor and recipient should be explored. It is important to ascertain whether the donor is informed about any plans that may exist relating to future contact. The assessment should occur after couples have concluded their own reproductive attempts and have clearly indicated their desire to donate embryos.

D. The clinical interview should include a psychosocial history of both partners, which addresses:

1. Family history.
2. Educational background.
3. Assessment of stability.
4. Motivation to donate.
5. Current life stressors and coping skills.
6. Difficult or traumatic reproductive history.
7. Interpersonal relationships.
8. Sexual history.
9. History of major psychiatric and personality disorders.
10. Substance abuse in donor or first-degree relatives.
11. Legal history.
12. History of abuse or neglect.
13. Emotional attachment to embryo.

E. If indicated, psychological testing is recommended to document and validate in a standardized objective manner the information gathered from the clinical interview and should include an objective personality test and other self-report measures to assess potential instability or psychopathology.

F. Relative exclusion criteria for an embryo donor include:

1. Presence of significant psychopathology.
2. Positive family history of heritable psychiatric disorders.
3. Substance abuse.
4. Two or more first-degree relatives with substance abuse.
5. Current use of psychoactive medications.

6. History of sexual or physical abuse with no professional treatment.
7. Excessive stress.
8. Marital instability.
9. Impaired cognitive functioning.
10. Mental incompetence.
11. High-risk sexual practices.

G. A minimum 3-month waiting period with appropriate follow-up assessment is recommended between the time a couple signs the consent form to donate embryos and the actual donation to a recipient couple.

H. Physicians and employees of an infertility practice may not participate in embryo donation (as donors or recipients) within that practice.

I. Donors should not be compensated for their donated embryos.

J. Donors should be at least 21 years of age.

K. All potential donor couples should be advised at the time of the IVF procedure that additional screening and testing may be required if they elect to donate their embryos. The couple should be counseled about their possible ineligibility to donate embryos.

II. Recipients and their partners

A. Recipients of donor embryos and their partners should receive counseling about the potential psychosocial implications.

B. The decision to proceed with embryo donation is complex, and patients may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all patients considering embryo donation. The assessment should include a clinical interview and, where appropriate, psychological testing. The physician should require psychological consultation for patients in whom there appear to be factors that warrant further evaluation.

C. The recipient and her partner should be counseled about their subsequent feelings concerning the medical conditions that made necessary the use of donor embryos.

D. The impact of treatment failure also should be addressed, including coping with treatment termination, the grieving process, and developing alternatives for the future.

E. Relative issues, such as the impact of the relationship between known donors, recipients, and offspring, should be explored.

F. This assessment should attempt to exclude significant psychiatric illness and current substance abuse and to evaluate their ability to cope with the stress of ART.

G. Recipients of donor embryos should be advised of screening and testing requirements and be prepared either to not use or to assume the risks related to the use of donor embryos.

Acknowledgments: This report was developed under the direction of the Practice Committee of the American Society for Reproductive Medicine (ASRM) in collaboration with the Society for Assisted Reproductive Technology (SART) as a service to its members and other practicing clinicians. Although this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations. The Practice Committees and the Board of Directors of ASRM and SART have approved this report.

This document was reviewed by ASRM members and their input was considered in the preparation of the final document. The following members of the ASRM Practice Committee participated in the development of this document. All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.

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APPENDIX A

MINIMUM GENETIC TESTING FOR GAMETE AND EMBRYO DONORS (2–4)

The American Society for Reproductive Medicine; Birmingham, Alabama

I. The donor
   A. Should not have any major Mendelian disorder. Mendelian disorders fall into the following categories:
      a. Autosomal dominant or X-linked disorders. Providers should be aware that some autosomal dominant or X-linked disorders can have variable expressivity (meaning that mutation carriers may not have noticeable symptoms) or have an age of onset that extends beyond the age of the donor (one example is Huntington disease).
      b. Autosomal recessive disorders. Donors who are heterozygous need not necessarily be excluded if the reproductive partner has had appropriate carrier screening. The recipient and reproductive partner (as appropriate) should be counseled about the accuracy of the carrier screening test and the residual risk to be a carrier following a negative test. Counseling regarding residual risk is complex and may be best provided by a genetic counselor.
   B. Should not have (or have had) any major malformation of complex cause (multifactorial/polygenic), such as spina bifida or cardiac malformation. A major malformation is defined as one that carries serious functional or cosmetic handicap. However, the definition of "major" is a matter of judgment.
   C. Should not have any significant familial disease with a major genetic component.
      Note: Assessment of hereditary risk factors by family history review is performed best by a genetic counselor. However, this screening may be performed by any professional trained in medical genetics at the discretion of the individual program.
   D. Should not have a known karyotypic abnormality that may result in chromosomally unbalanced gametes. In the general population, the chance of having a chromosomal rearrangement that could be transmitted in unbalanced form to offspring is small, provided the family history is negative for risk factors. Therefore, routine karyotyping of all donors is optional.
   E. Should undergo general population and ethnicity (ancestry)-based genetic screening. Donors should give informed consent prior to carrier screening. Informed consent should include discussion of the natural history of the condition being screened, carrier frequency in the respective ethnic group, detection rate of the test, residual risk to be a carrier when testing negative, and options for persons testing positive. If a prospective donor is identified as a carrier, genetic counseling for both the donor and recipient is recommended (6).
      The recommended list of tests may change as tests for other disorders are developed. Guidelines regarding ethnicity and population-based genetic screening are published by the American Congress of Obstetricians and Gynecologists (http://www.acog.org) and the American College of Medical Genetics (http://www.acmg.net/). All gamete donors should be evaluated by the current tests recommended at the time of the donation.
      Note: It is not appropriate to screen gamete donors for adult onset conditions (such as cancer predisposition, Huntington disease, etc.) without full consent of the gamete donor, including formal genetic counseling (7).
   F. Should be generally healthy and young. Advanced maternal age is associated with an increased risk for aneuploid offspring. Advanced paternal age is associated with a moderately increased risk for new mutations in offspring, and an emerging body of evidence suggests an increased risk for complex disorders, including some congenital anomalies, schizophrenia, autism spectrum disorders, and specific forms of cancer.

II. The donor's first-degree relatives (parents, siblings, and offspring) should be free of:
   A. Mendelian disorders as described in Section I.A.
   B. Major malformations as described in Section I.B.
   C. Significant familial disease with a major genetic component.
   D. A chromosomal abnormality, unless the donor has a normal karyotype.
   E. Mental retardation of undocumented etiology.

If family history reveals a disorder for which definitive testing is available, then it is appropriate to refer the prospective donor for genetic counseling for that specific disorder. Testing without a formal genetic consultation would be inappropriate. Genetic test results may determine the appropriateness of using that donor.

Recommendations for practices utilizing gestational carriers: a committee opinion

Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology

American Society for Reproductive Medicine, Birmingham, Alabama

This document provides the latest recommendations for evaluation of gestational carriers and intended parents. It incorporates recent information from the US Centers for Disease Control and Prevention, the US Food and Drug Administration, and the American Association of Tissue Banks, with which all programs offering gestational carrier services must be thoroughly familiar. This document replaces the previous document of the same name, last published in 2015 (Fertil Steril® 2015; 103:e1–8). (Fertil Steril® 2017;107:e3–10. ©2016 by American Society for Reproductive Medicine.)

STATEMENT OF PURPOSE

The following recommendations are intended to provide guidance for when it is appropriate to consider using a gestational carrier, provide guidelines for screening and testing of genetic parents and gestational carriers to reduce the possibility of complications, and to address the complex medical and psychological issues that confront the gestational carrier and intended parents, as well as the children. A gestational carrier is defined as a woman who carries a pregnancy and is not sexually intimate with the genetic parents or gamete donors. These guidelines incorporate recent information about optimal screening and testing for sexually transmitted infections (STI) and psychological assessments.

The current document represents an effort to make the screening procedures for individuals involved in third-party reproduction using a gestational carrier more consistent and incorporates recent information from the US Centers for Disease Control and Prevention (CDC), US Food and Drug Administration (FDA), and American Association of Tissue Banks (AATB). These recommendations use terminology from the federal agencies in addition to the AATB. In that context, the term "screening" refers to specific historical factors that place an individual at a higher risk for a given disease, such as human immunodeficiency virus (HIV) and transmissible spongiform encephalopathy (TSE), or Creutzfeldt-Jakob disease (CJD). "Testing" refers to specific laboratory studies, such as serologic tests. The distinction between screening and testing is consistent within the document. The term "ineligible" does not mean excluded, but eligible with appropriate informed consent. These recommendations for the screening and testing of gestational carriers and the genetic parents apply to individuals in the United States. Because the prevalence of STIs and genetic diseases may vary in other geographic areas, these recommendations may not be appropriate for other countries or individuals who come to the United States from other countries. Whereas the FDA does not require screening or testing of the gestational carrier, the American Society for Reproductive Medicine (ASRM) recommends testing these individuals as described.

Other areas where the ASRM recommendations may be more stringent than the FDA minimum requirements are noted in the text. Additionally, state requirements may be more restrictive than the FDA, and clinics should be aware of minimum screening and testing requirements for their state.

1. Indications for the use of a gestational carrier
   a. Gestational carriers may be used when a true medical condition precludes the intended parent from carrying a pregnancy or would pose a significant risk of death or harm to the woman or the fetus. The indication must be clearly documented in the patient's medical record. Examples of such medical indications would include:

Received November 3, 2016; accepted November 3, 2016; published online January 6, 2017.
Reprint requests: Practice Committee, American Society for Reproductive Medicine, 1209 Montgomery Hwy, Birmingham, Alabama 35216 (E-mail: ASRM@asrm.org).

Fertility and Sterility® Vol. 107, No. 2, February 2017 0015-0282/$36.00

http://dx.doi.org/10.1016/j.fertnstert.2016.11.007

i. Absence of uterus (congenital or acquired)
ii. Significant uterine anomaly (e.g., irreparable Asherman syndrome; unicornuate uterus associated with recurrent pregnancy loss)
iii. Absolute medical contraindication to pregnancy (e.g., pulmonary hypertension)
iv. Serious medical condition that could be exacerbated by pregnancy or cause significant risk to the fetus
v. Biologic inability to conceive or bear a child, such as single male or homosexual male couple

b. Gestational carriers may be considered when an unidentified endometrial factor exists, such as for patients with multiple unexplained previous in vitro fertilization (IVF) failures despite transfer of good-quality embryos.
c. No owner, operator, laboratory director, or employee of the practice may serve as a carrier or intended parent in that practice.

2. Intended parents
a. Psychosocial education

The decision to use a gestational carrier is complex, and patients and their partners (if applicable) may benefit from psychosocial education to aid in this decision. The physician should strongly recommend psychosocial education and counseling by a qualified mental health professional to all intended parents. The assessment should include a clinical interview and, where appropriate, psychological testing. Psychological test data should be handled in accordance with American Psychological Association ethical standards (1). The clinician should refer patients in whom factors appear to warrant further evaluation to a qualified mental health professional. The potential impact of the relationship between the intended parent and carrier should be explored, as should any plans that may exist relating to disclosure and future contact (see section titled "Psychosocial consultation for gestational carriers and intended parents," 4.a.).

b. Screening and testing of genetic parents.
i. Genetic parents should undergo appropriate genetic evaluation. Universal testing should be considered for diseases that are common in all genetic backgrounds (such as cystic fibrosis and spinal muscular atrophy). Targeted testing based on ethnicity should be considered for diseases that are common to certain ethnicities (such as sickle cell, TaySachs, etc.).
ii. The genetic parents should undergo a complete medical evaluation, including a thorough history and physical examination, to ensure that they are healthy enough to proceed with procedures involving assisted reproductive technology (ART).
iii. Genetic parents must be screened in the same manner as gamete donors (2–4). Prospective genetic parents with any identified risk factors based on screening questionnaires are considered ineligible according to guidelines issued by the FDA. According to current FDA guidelines, embryos created by such individuals can still be transferred into a gestational carrier provided that the tissue is labeled to indicate any associated increased risks and that physicians transferring the embryos are aware of the status of the results. Although the FDA does not require that the gestational carrier be informed of the results of the screening, ASRM recommends that embryos created using gametes from individuals considered ineligible should only be transferred to a gestational carrier who is adequately informed and counseled regarding the associated potential risks.
iv. Before acceptance, and within 6 months of creating the embryos to be transferred, the genetic parents must undergo a complete physical examination (Society for Assisted Reproductive Technology [SART] physical examination forms, www.sart.org). When any of the following is present, the genetic parents are considered ineligible (see above).
1. Physical evidence for risk of sexually transmitted disease, such as genital ulcerative lesions, herpes simplex, chancroid, and urethral discharge
2. Physical evidence of risk for syphilis or evidence of syphilis
3. Physical evidence of anal intercourse in the male partner, including perianal condylomata
4. Physical evidence of nonmedical percutaneous drug use, such as needle tracks; the examination should include examination of tattoos, which might obscure needle tracks
5. Physical evidence of recent tattooing, ear piercing, or body piercing (within the past 12 months) where sterile technique was not used
6. Disseminated lymphadenopathy
7. Unexplained oral thrush
8. Blue or purple spots consistent with Kaposi sarcoma
9. Unexplained jaundice, hepatomegaly, or icterus
10. Large scab consistent with recent history of smallpox immunization
11. Eczema vaccinatum, generalized vesicular rash, severely necrotic lesion (consistent with vaccinia necrosum), or corneal scarring (consistent with vaccinial keratitis)

v. Laboratory testing

There is no method that completely ensures that infectious agents will not be transmitted to the gestational carrier. However, the following guidelines, combined with an adequate medical history and

specific exclusion of individuals at high risk for HIV and other STIs should significantly reduce these risks. The FDA requires that the following tests be performed within 30 days of oocyte retrieval and within 7 days of sperm collection, using methods approved specifically for purposes of determining donor eligibility, and that negative results be documented before use of the genetic parent's gametes. Tests using nucleic acid testing (NAT) technology to target sequences located in specific genes adequately and appropriately reduce the risk of transmission of these relevant communicable agents. The list of test methods approved by the FDA for the purpose of donor screening is available at the following website, http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/UCM080466

1. Human immunodeficiency virus (HIV)-1 antibody and NAT
2. HIV-2 antibody
3. HIV group O antibody. Establishments that do not use an FDA-licensed test for HIV group O antibodies must evaluate the genetic parents for risk associated with HIV group O infection with additional screening questions (see "risk factor questionnaire for donors," available at www.sart.org).
4. Hepatitis C antibody and NAT
5. Hepatitis B surface antigen
6. Hepatitis B core antibody immunoglobulin G [IgG] and immunoglobulin M [IgM]
7. Serologic test for syphilis
8. Additional testing for the female genetic parent must include:
   a. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* NAT on urine or a swab obtained from the cervix, urethral meatus, or vagina. Because there are no tests licensed, approved, or cleared by the FDA for screening donors for *N. gonorrhea* and *C. trachomatis*, the laboratory must use an FDA-licensed, -approved, or -cleared test labeled for the detection of these organisms in an asymptomatic, low-prevalence population.
9. Additional testing for the male genetic parent must include:
   a. *N. gonorrhoeae* and *C. trachomatis* testing using a NAT on urine or a swab obtained from the urethral meatus using an FDA-licensed, -approved, or -cleared test labeled for the detection of these organisms in an asymptomatic, low-prevalence population.
   b. (Human T-lymphotropic virus HTLV)-1 and HTLV-2
   c. Cytomegalovirus (CMV) (IgG and IgM)
10. ASRM recommends testing the genetic parents' blood type and Rhesus (Rh) factor. If there is the potential for Rh incompatibility, couples should be informed about the obstetric significance of this condition.

vi. Managing laboratory results

1. A positive test should be confirmed before notifying the potential genetic parent. If a test is confirmed positive, the individual should be referred for appropriate counseling and management.
2. Individuals with false-positive test results for syphilis using non-treponemal assays that are confirmed to be negative using a treponemal-based assay are considered eligible.
3. Individuals with positive tests for syphilis, *N. gonorrhoeae*, or *C. trachomatis* should be treated, retested, and deferred from creating embryos for use in a gestational carrier for 12 months after documentation that treatment was successful before being reconsidered. If evidence is presented documenting successful treatment more than 12 months prior, no further deferral is needed as long as current testing does not indicate an active infection.
4. Men who test positive for active CMV infection (positive urine or throat culture or paired serum samples demonstrating a 4-fold rise in IgG antibody and IgM antibody at least 30% of the IgG level) should be excluded until signs of active infection are no longer present. There are many strains of CMV, and superinfection in the gestational carrier is possible even if she is CMV IgG positive. The risk of CMV transmission and newborn CMV infection from an embryo transfer is extremely low, and such infants appear to have no significant illness or other abnormality.
5. Individuals who initially test positive for HIV-1 antibody and NAT, HIV-2 antibody, HIV group O antibody, hepatitis C antibody and NAT, hepatitis B surface antigen, hepatitis B core antibody (IgG and IgM), and HTLV-1 and HTLV-2 are considered ineligible. According to current FDA guidelines, embryos created by such individuals can still be transferred into a gestational carrier provided that the tissue is labeled to indicate any associated increased risks and that physicians transferring the embryos are aware of the status of the results. Although the FDA does not require that recipients be informed of the test results, in the opinion of the ASRM, recipients must be informed and counseled appropriately before such embryos can be transferred into a gestational carrier.

vii. Quarantining of embryos

All potential gestational carriers should be offered the option of cryopreserving and

quarantining embryos derived from the genetic parents for 180 days, with release of embryos only after the genetic parents have been retested with confirmed negative results (see section on Laboratory Testing for intended parents, 2.v.1–10). However, couples also should be informed that historically embryo cryopreservation had lower implantation rates. The gestational carrier should be counseled appropriately in the event of seroconversion of a genetic parent after cryopreservation of the embryos.

viii. Record keeping

The FDA requires that records pertaining to each genetic parent (screening and test results) be maintained for at least 10 years. However, in the opinion of the ASRM, a permanent record of each intended parent's initial screening, testing, and subsequent follow-up evaluations should be maintained. To the extent possible, the clinical outcome for each cycle should be recorded. A mechanism must exist to maintain such records as a future medical resource for any offspring produced.

1. Protection of confidentiality: Individuals participating in gestational carrier programs should be assured that their confidentiality and medical information will be protected insofar as federal and local statutes permit. Medical records detailing the eligibility of the intended parents should be maintained as stipulated by federal and local requirements.

ix. Legal issues and informed consent

1. The genetic parents should be counseled regarding the risks and adverse effects of ovarian stimulation and retrieval, with such counseling documented in the patients' permanent medical records.
2. Intended parents must have ongoing legal counsel by an appropriately qualified legal practitioner who is experienced with third-party reproduction and licensed to practice in the relevant state or states, or in the event of an international arrangement, in addition to any relevant states, in the intended parent(s)' home country.

3. Gestational carriers

a. Selection and evaluation of gestational carriers

i. Psychosocial evaluation and counseling by a qualified mental health professional area strongly recommended for all potential gestational carriers and their partners. The assessment should include a clinical interview and, where appropriate, psychological testing. Psychological test data should be handled in accordance with American Psychological Association ethical standards (1). The clinician should refer patients in whom factors appear to warrant further evaluation to a qualified mental health professional. The potential impact of the relationship between the gestational carrier and intended parent should be explored, as well as any plans that may exist relating to disclosure and future contact (see section on Laboratory Testing, 4.a.).

1. The psychosocial evaluation and counseling should consider the impact of the pregnancy on family and community dynamics.
2. Carriers must be of legal age, and preferably between the ages of 21 and 45 years. Certain situations may dictate the use of a carrier older than 45 years of age, but all parties involved must be informed about the potential risks of pregnancy with advancing maternal age.
3. Ideally, the carrier should have had at least one, term, uncomplicated pregnancy before being considered as a gestational carrier for another couple.
4. Ideally, the carrier should not have had more than a total of five previous deliveries or three deliveries via cesarean section.
5. Ideally, the carrier should have a stable family environment with adequate support to help her cope with the added stress of pregnancy.

b. Screening and testing of a gestational carrier

i. A complete personal and sexual history should be obtained to identify individuals who might be at high risk for HIV, STIs, or other acquired infections that might be transmissible to the fetus. Although the FDA does not require screening or testing of gestational carriers for possible transmissible infectious diseases to the fetus, ASRM recommends testing of all gestational carriers and their partners within 30 days before embryo transfer to protect the health and interests of all parties involved (see www.sart.org for screening questionnaire).

ii. Before acceptance, the potential gestational carrier should undergo a complete medical evaluation by a qualified medical professional and be cleared for pregnancy before being considered.

iii. The carrier should not be used when any of the following findings are present:

1. Physical evidence for risk of sexually transmitted disease, such as genital ulcerative lesions, herpes simplex, chancroid, and urethral discharge
2. Physical evidence of risk for syphilis or evidence of syphilis
3. Physical evidence of nonmedical percutaneous drug use, such as needle tracks; the examination should include examination of tattoos, which might obscure needle tracks
4. Physical evidence of recent tattooing, ear piercing, or body piercing (within the past 12 months) where sterile technique was not used

5. Disseminated lymphadenopathy
6. Unexplained oral thrush
7. Blue or purple spots consistent with Kaposi sarcoma
8. Unexplained jaundice, hepatomegaly, or icterus
9. Large scab consistent with recent history of smallpox immunization
10. Eczema vaccinatum, generalized vesicular rash, severely necrotic lesion (consistent with vaccinia necrosum), or corneal scarring (consistent with vaccinial keratitis)

iv. Laboratory testing

There is no method to completely ensure that the carrier will not have infectious agents that could be transmitted to the fetus. However, the following guidelines, combined with an adequate medical history and specific exclusion of individuals at high risk for HIV and other STIs, should dramatically reduce these risks. The ASRM recommends the following tests be performed on the carrier and her partner and that negative results be documented before use of the gestational carrier.

1. Carrier and her sexually intimate partner
   a. HIV-1 antibody as well as NAT
   b. HIV-2 antibody
   c. HIV group O antibody
   d. HTLV-1 and HTLV-2 (male partner only)
   e. Hepatitis C antibody and NAT
   f. Hepatitis B surface antigen
   g. Hepatitis B core antibody (IgG and IgM)
   h. Serologic test for syphilis
   i. CMV (IgG and IgM)
   j. *N. gonorrhoeae* and *C. trachomatis* testing using NAT on urine or a cervical or urethral swab using an FDA-licensed, -approved, or -cleared test labeled for the detection of these organisms in an asymptomatic, low-prevalence population
2. Carrier only
   a. Blood type and Rh factor. If there is the potential for Rh incompatibility, couples should be informed about the obstetric significance of this condition.
   b. Papanicolaou smear
   c. Mammogram according to American College of Obstetricians and Gynecologists guidelines
   d. Titers for varicella and rubella
   e. Urine drug screen

v. Managing laboratory results

1. A positive test should be confirmed before notifying the individual. If a test is confirmed positive, the individual should be referred for appropriate counseling and management.
2. Individuals who test positive for HIV-1, HIV-2, HIV group O antibody, hepatitis B, or hepatitis C should generally not be allowed to serve as gestational carriers. Exceptions to this recommendation require careful counseling, informed consent, and documentation of risks in the medical records.
3. Individuals found to be positive for syphilis, *N. gonorrhoeae*, or *C. trachomatis* should be treated, retested, and deferred from use as a gestational carrier for 12 months after documentation that treatment was successful before being reconsidered. If evidence is presented documenting successful treatment more than 12 months prior, no further deferral is needed as long as current testing does not indicate an active infection.
4. Individuals with false-positive results for syphilis using non-treponemal assays that are confirmed to be negative using a treponemal-based assay are eligible to be used as gestational carriers.
5. Women or their partners who test positive for active infection with CMV (positive urine or throat culture or paired serum samples demonstrating a 4-fold rise in IgG antibody and IgM antibody at least 30% of the IgG level) should be excluded from serving as a carrier until signs of active infection are no longer present.

vi. Legal issues and informed consent

a. Gestational carriers and their partners/spouses should be advised explicitly of the risks of the procedures and medications as well as potential complications of pregnancy, including the possibility of prolonged bed rest or hospitalization. This counseling should be documented in the patients' permanent medical record.
b. Gestational carriers must have ongoing independent legal representation by an appropriately qualified legal practitioner who is experienced with gestational carrier contracts and who is licensed in the relevant state or states, or in the event of an international arrangement, in addition to any relevant states, the intended parent(s)' home country.
c. Special consideration should be given to transferring a single embryo in an effort to limit the risks of multiple pregnancy for the carrier. After appropriate counseling and agreement by all parties, additional embryos may be transferred based on the age of the genetic parent, in an effort to improve the probability of pregnancy.
d. Protection of confidentiality: Individuals participating in gestational carrier programs should be assured that their confidentiality and medical/psychological information will be protected insofar as federal and local statutes permit.

e. Issues regarding screening and testing of the fetus during pregnancy should be discussed and the discussion documented in the medical record or legal contract between the carrier and the intended parents. Contingency plans for management of specific complications (i.e., abnormal genetic testing of the fetus, birth defects, etc.) should be discussed and agreed upon in advance of treatment. The possibility of pregnancy termination for pregnancy complications (in the gestational carrier or fetus) or for multifetal gestations also should be discussed before treatment.

f. Behavior of the gestational carrier: Individuals who smoke, consume alcohol (>1 drink per day), or have other potentially harmful habits should not be considered as gestational carriers. Activity of the carrier (travel, exercise, diet, sexual activity, vitamin supplements, etc.) should be discussed between the parties and agreed upon in advance of treatment.

g. Compensation to the gestational carrier: Compensation to the gestational carrier should be agreed upon in writing in the legal contract between the intended parents and carrier before any treatment begins. The amount of compensation paid to the carrier can be prorated based on the procedure(s) performed.

vii. Quarantining of embryos

All potential gestational carriers should be offered the option of cryopreserving and quarantining embryos derived from the intended parents for 6 months, with release of embryos only after the intended parents have been retested with confirmed negative results (see section on Laboratory testing of gestational carriers, 3.b.iv.1.a-j.). In the event of seroconversion of an intended parent after cryopreservation of the embryos, the ASRM recommends that the embryos should not be transferred into a gestational carrier.

viii. Record keeping

A permanent record of each gestational carrier's initial selection process, medical evaluation, eligibility, and subsequent follow-up evaluations should be maintained indefinitely. The clinical outcome for each cycle should be recorded. A mechanism must exist to maintain such records as a future medical resource for any offspring produced.

4. Psychosocial consultation for gestational carriers and intended parents

a. Psychosocial consultation for intended parents includes:

i. A clinical interview and psychological assessment including the intended parent(s)' history of infertility and methods of coping

ii. Psychological evaluation of each intended parent is strongly recommended as a means to alert the team to significant psychological issues that could compromise successful collaboration with the gestational carrier

iii. Informing intended parent(s) of potential psychological issues and risks associated with the gestational carrier process

iv. Discussion of the medical protocol, scheduling demands, risks of cancelled cycles or unsuccessful cycles, number of embryos transferred, multiple pregnancy, multifetal pregnancy reduction, prenatal diagnostic testing, and elective termination

v. Requirement of intended parent(s)' agreement with the gestational carrier regarding all medical issues

vi. Definition of the role/function of qualified mental health professionals

vii. Counseling topics include:

1. Management during pregnancy of expectations and relationship with the gestational carrier and her family
2. Meeting the emotional and physical needs of the gestational carrier and her family
3. Understanding the gestational carrier's right to make choices for her body over the rights of the intended parents
4. Rights of the gestational carrier to refuse or to accept medical interventions or testing
5. Number of embryos to be transferred and number of cycles planned to be determined by the gestational carrier and physician
6. Multiple pregnancy and associated risks
7. Multifetal pregnancy reduction and discussion of psychological risks and concerns
8. Possibility of abortion in the event of an abnormal fetus
9. Gestational carrier's behavior during pregnancy and methods for resolving conflicts (e.g., eating habits, prescription drugs, alcohol)
10. Disclosure to offspring
11. Disclosure to family members and friends
12. Expectations of relationship between gestational carrier, intended parent(s), and children after birth
13. Need for gestational carrier and her children to interact with baby after birth
14. Disposition of extra embryos
15. Need for separate legal consultation and a written contract
16. Potential guilt reaction of gestational carrier associated with failed attempts or problems that may arise
17. Matching of gestational carrier and intended parent(s)
18. Relationship issues, expectations, and impact of failed cycle

b. Criteria for rejection of intended parents
    i. Absolute criteria for rejection include:
        1. Inability to maintain respectful and caring relationship with gestational carrier
        2. Abnormal psychological evaluation as determined by the qualified mental health professional
        3. Unresolved or untreated addiction, child abuse, sexual or physical abuse, depression, eating disorder
        4. Unresolved or untreated major depression, bipolar disorder, psychosis, or significant anxiety disorder or personality disorder
        5. Current marital or relationship instability
        6. Intended parent(s)' failure to agree with gestational carrier's decision on number of embryos transferred
    ii. Relative criteria for rejection include:
        1. Ongoing legal disputes
        2. Significant and ongoing problematic interpersonal relationships
        3. History of noncompliance or ongoing problematic interactions with program or medical staff
c. Psychosocial consultation for gestational carriers includes:
    i. Informing the potential gestational carrier and her partner regarding the potential psychological issues and risks associated with the process
    ii. Discussion of the medical protocol, including scheduling demands, risks of cancelled cycle and unsuccessful cycle, multiple pregnancy, multifetal pregnancy reduction, prenatal diagnostic testing, and elective termination
    iii. Discussion of requirement of intended parent(s)' agreement with gestational carrier regarding all medical issues
    iv. Definition of role/function of the qualified mental health professional
    v. Counseling topics include:
        1. Management of the relationship between the intended parent(s) and the gestational carrier; past, present, and future
        2. Coping appropriately with the pregnancy
        3. Risks of attachment to the child and risk to the gestational carrier's children
        4. Impact on gestational carrier's marriage or partnership
        5. Impact on gestational carrier's employment
        6. The balance between the gestational carrier's right to privacy and the intended parent(s)' right to information
    vi. Offer of group/individual counseling with qualified mental health professional
    vii. Separate, ongoing legal counsel and representation for gestational carrier and intended parents
    viii. Informing the gestational carrier of source of gametes before legal consent
    ix. Social history, including family of origin
    x. Psychiatric history including prior hospitalizations, suicide attempts, medication, and counseling
    xi. Occupational and financial history
    xii. Sexual and reproductive history
    xiii. History of smoking, substance use, and physical, emotional, or sexual abuse
    xiv. History of postpartum disorder(s) and other unresolved negative reproductive events
    xv. Religious beliefs that may influence behavior
    xvi. Maturity, judgment, assertiveness, and decision-making skills
    xvii. Legal history
    xviii. Negative medical history as it relates to the psychosocial adjustment of being a gestational carrier (e.g., bed rest, gestational diabetes, preeclampsia)
    xix. Personality style and coping skills, capacity for empathy
    xx. Current major life stressors or anticipated changes within the next 2 years
    xxi. Previous gestational carrier experience or application to another facility
    xxii. Motivation to become a gestational carrier
    xxiii. Support of significant other
    xxiv. Social network
    xxv. Desire for more children of her own
    xxvi. Anticipated impact of gestational experience upon her children and significant other
    xxvii. Anticipated type and duration of relationship with intended parents
    xxviii. Ability to separate from and relinquish the child
    xxix. Anticipated feelings toward the child
    xxx. Feelings about multiple pregnancy, bed rest, hospitalization, and pregnancy loss
    xxxi. Feelings about possible sexual abstinence
    xxxii. Feelings and decisions about termination of pregnancy, multifetal pregnancy reduction, amniocentesis, chorionic villi sampling, and other prenatal diagnostic testing
    xxxiii. Reactions to the possibility of becoming infertile as a result of the process
    xxxiv. Agreement with the financial compensation arrangement
d. Criteria for rejection of a gestational carrier
    i. Absolute rejection criteria include:
        1. Cognitive or emotional inability to comply or consent
        2. Evidence of financial or emotional coercion
        3. Abnormal psychological evaluation/testing as determined by the qualified mental health professional
        4. Unresolved or untreated addiction, child abuse, sexual abuse, physical abuse, depression, eating disorders, or traumatic pregnancy, labor and/or delivery

5. History of major depression, bipolar disorder, psychosis, or a significant anxiety disorder
6. Current marital or relationship instability
7. Chaotic lifestyle, current major life stressor(s)
8. Inability to maintain respectful and caring relationship with intended parent(s)
9. Evidence of emotional inability to separate from/surrender the child at birth

ii. Relative rejection criteria include:

1. Failure to exhibit altruistic commitment to become a gestational carrier
2. Problematic personality disorder
3. Insufficient emotional support from partner/spouse or support system
4. Excessively stressful family demands
5. History of conflict with authority
6. Inability to perceive and understand the perspective of others
7. Motivation to use compensation to solve own infertility
8. Unresolved issues with a negative reproductive event

Acknowledgments: This report was developed under the direction of the Practice Committee of the American Society for Reproductive Medicine (ASRM) in collaboration with the Society for Assisted Reproductive Technology (SART) as a service to its members and other practicing clinicians. Although this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations. The Practice Committees and the Board of Directors of ASRM and SART have approved this report.

This document was reviewed by ASRM members and their input was considered in the preparation of the final document. The following members of the ASRM Practice Committee participated in the development of this document. All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.

Samantha Pfeifer, M.D.; Samantha Butts, M.D., M.S.C.E.; Gregory Fossum, M.D.; Clarisa Gracia, M.D., M.S.C.E.; Andrew La Barbera, Ph.D.; Jennifer Mersereau, M.D.; Randall Odem, M.D.; Richard Paulson, M.D.; Alan Penzias, M.D.; Margareta Pisarska, M.D.; Robert Rebar, M.D.; Richard Reindollar, M.D.; Mitchell Rosen, M.D.; Jay Sandlow, M.D.; Michael Vernon, Ph.D.

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4. Society for Assisted Reproductive Technology. Male donor physical examination form. Available at: http://www.sart.org. Accessed August 9, 2016.

A01071 Summary:

BILL NO A01071C

SAME AS SAME AS

SPONSOR Paulin (MS)

COSPNSR Zebrowski, Weprin, Galef, Otis, Stirpe, Benedetto, Bronson, Mosley, Ortiz, Dinowitz, Rosenthal L, Steck, Simon, Woerner, Carroll, De La Rosa, Simotas, Lavine, Epstein, Dickens, Reyes, Walker, Rodriguez, Stern, Pichardo, Cruz, Blake, Quart, Niou, Sayegh, D'Urso, Buchwald

MLTSPNSR Englebright, Gottfried, Peoples-Stokes, Thiele

Add Art 5-C Parts 1 - 7 §§581-101 - 581-704, Fam Ct Act; rpld §73, amd §§121 - 124, Art 8 Head, Dom Rel L; amd §§4135-b & 4365, add Art 25-B §2599-cc, Pub Health L; add Art 44 §§1400 - 1403, Gen Bus L

Relates to judgments of parentage for children conceived through assisted reproduction or pursuant to surrogacy agreements; restricts genetic surrogate parenting contracts; regulates surrogacy programs; repeals provisions relating to the legitimacy of children born by artificial insemination.

A01071 Actions:

BILL NO A01071C

01/14/2019 referred to judiciary
02/22/2019 amend (t) and recommit to judiciary
02/22/2019 print number 1071a
02/27/2019 reported referred to codes
05/15/2019 amend (t) and recommit to codes
05/15/2019 print number 1071b
06/10/2019 amend (t) and recommit to codes
06/10/2019 print number 1071c
01/08/2020 referred to codes

A01071 Memo:

NEW YORK STATE ASSEMBLY
MEMORANDUM IN SUPPORT OF LEGISLATION
submitted in accordance with Assembly Rule III, Sec 1(f)

BILL NUMBER: A1071C

SPONSOR: Paulin (MS)

TITLE OF BILL: An act to amend the family court act, in relation to judgments of parentage of children conceived through assisted reproduction or pursuant to surrogacy agreements; to amend the domestic relations law, in relation to restricting genetic surrogate parenting contracts; to amend the public health law, in relation to voluntary acknowledgments of parentage, gestational surrogacy and regulations concerning ova donation; to amend the general business law, in relation to the regulation of surrogacy programs; and to repeal section 73 of the domestic relations law, relating to legitimacy of children born by artificial insemination

PURPOSE OR GENERAL IDEA OF BILL:

To legally establish a child's relationship to his or her parents where the child is conceived through assisted reproduction, except for children born to a person acting as surrogate who contributed the gametes used in conception.

SUMMARY OF SPECIFIC PROVISIONS:

Section 1 of the bill adds a new article 5-C to the Family Court Act entitled "Judgments of Parentage for Children Conceived Through Assisted Reproduction or Pursuant to Surrogacy Agreements."

PART ONE: GENERAL PROVISIONS

-Section 581-101 establishes the purpose of the bill.

-Section 581-102 establishes definitions used throughout article 5-C.

PART TWO: JUDGMENT OF PARENTAGE

-Section 581-201 establishes civil proceedings to adjudicate the legal parentage of a child born via assisted reproduction or a surrogacy agreement (i.e. judgments of parentage).

-Section 581-202 establishes the conditions under which a proceeding for judgment of parentage may be commenced and adjudicated to determine parentage of a child conceived through assisted reproduction.

-Section 581-203 establishes the conditions under which a proceeding for judgment of parentage may be commenced and adjudicated to determine parentage of a child conceived pursuant to a surrogacy agreement.

-Section 581-204 allows parents who are each others' spouses to obtain a judgment of parentage, notwithstanding any other legal presumptions of parentage.

-Section 581-205 states that court records related to judgments of

parentage are sealed, but parties to the proceeding and resulting children have the right to inspect the record, including, but not limited to, the name of the person acting as surrogate and any known donors.

-Section 581-206 allows judgment of parentage proceedings to be initiated in either Supreme Court or Family Court.

PART THREE: CHILD OF ASSISTED REPRODUCTION

-Section 581-301 clarifies that Article 5-C does not apply to the birth of a child conceived through sexual intercourse.

-Section 581-302 clarifies that a donor in not a legal parent of a child conceived through assisted reproduction.

-Section 581-303 clarifies that a person who provides gametes for, or consents to, assisted reproduction with the intent to be a parent of the resulting child with the consent of the gestating parent is a legal parent of the resulting child.

-Section 581-304 establishes when consent to assisted reproduction is presumed and how to prove consent when it is not presumed.

-Section 581-305 places limitations on a spouse's ability to dispute the parentage of a child born through assisted reproduction.

-Section 581-306 discusses the effect of embryo disposition agreements between intended parents which transfer legal rights and dispositional control of the embryo(s) to one intended parent.

-Section 581-307 clarifies that a person who consented to be a parent by assisted reproduction who dies before the transfer of gametes is not the legal parent of any resulting children unless they consented in a signed record to be the parent to children conceived through assisted reproduction after their death.

PART FOUR: SURROGACY AGREEMENT

-Section 581-401 authorizes surrogacy agreements that meet the requirements of this article, establishes that such agreements may provide for compensation, and clarifies that a surrogacy agreement shall not apply to the birth of a child conceived through sexual intercourse.

-Section 581-402 establishes the eligibility requirements for persons acting as surrogates and intended parents who wish to enter surrogacy agreements, including the requirement that the person acting as surrogate and at least one intended parent be United States citizens or lawful permanent residents.

-Section 581-403 establishes the requirements that must be met for a surrogacy agreement to be enforceable.

-Section 581-404 clarifies that if the person acting as surrogate gets married after executing a surrogacy agreement, or intended parents get separated or divorced after executing a surrogacy agreement, it does not affect the validity of the agreement or any of the rights, duties or responsibilities outlined in the agreement.

-Section 581-405 provides that any party to a surrogacy agreement may terminate the agreement before the person acting as surrogate has become pregnant.

-Section 581-406 clarifies that upon birth of a child under an enforcea ble surrogacy agreement, each intended parent is the legal parent of the

child and neither the person acting as surrogate or their spouse (if any) is the legal parent.

-Section 581-407 establishes that surrogacy agreements that don't meet the material requirements of Article 5-C are not enforceable, and in such cases the court will determine parentage based on the intent of the parties, taking into account the best interests of the child.

-Section 581-408 establishes that if there is no surrogacy agreement, the court will determine parentage of the child under New York law.

-Section 581-409 gives the Supreme Court jurisdiction to hear any dispute related to a surrogacy agreement other than disputes as to parentage, and clarifies that there is no specific performance remedy that would require a person acting as surrogate to either be impregnated, terminate or continue the pregnancy, or to reduce or retain the number of fetuses or embryos they are carrying.

PART FIVE: PAYMENT TO DONORS AND PERSONS ACTING AS SURROGATES

-Section 581-501 establishes that donors who enter into valid agreements to be a donor may reimbursed for economic losses incurred in connection with donation.

-Section 581-502 establishes that compensation to a donor or person acting as surrogate may be paid based on medical risks, physical discomfort, inconvenience and the responsibilities they are undertaking in connection with their participation in assisted reproduction. Such compensation must be reasonable and negotiated in good faith between parties, and cannot be conditioned upon the purported quality or traits of the gametes or embryos, or the actual genotypic or phenotypic characteristics of the donor or any resulting children.

PART SIX: SURROGATES' BILL OF RIGHTS

This part enumerates rights that apply to any person acting as surrogate in New York, and establishes that unless otherwise provided by law, any written or verbal agreement purporting to waive or limit any of the rights enumerated in this part are void as against public policy.

The rights enumerated in this part include: health and welfare decisions; independent legal counsel; health insurance and medical costs; counseling; life insurance; and termination of surrogacy agreements.

PART SEVEN: MISCELLANEOUS PROVISIONS

-Section 581-701 establishes that the article is to be construed liberally to secure the beneficial interests and purposes thereof for the best interests of the child.

-Section 581-702 is a severability clause.

-Section 581-703 establishes that the term "parent" as used in section 70 of the Domestic Relations Law includes parents established pursuant to this article.

-Section 581-704 establishes that unless context indicates otherwise, singular words may be interpreted as plural and vice versa.
Section 2 of the bill repeals section 73 of the Domestic Relations Law.

Sections 3 through 6 of the bill amend Article 8 of the Domestic Relations Law to no longer apply the legal prohibition on surrogacy contracts to surrogacy agreements authorized and regulated under section 1 of this bill, but continuing to render void and enforceable so called "traditional" surrogacy agreements where the person acting as surrogate

provided, the egg used in conceiving the resulting child.

Section 7 of the bill amends section 4135-b of the Public Health Law to update and modernize terminology throughout the section to reflect same-sex parents and conform the provisions of the section with the judgments of parentage and surrogacy agreements authorized and regulated in section 1 of this bill.

Section 8 of the bill amends the heading of article 8 of the Domestic Relations Law.

Section 9 of the bill adds a new article 44 to the General Business Law entitled "Regulation of Surrogacy Programs."

-Section 1400 establishes definitions used throughout the newly-created article.

-Section 1401 applies the newly-created article to any agency, agent, business or individual engaged in, arranging or facilitating transactions contemplated in a surrogacy agreement if the program does business in New York, a person acting as surrogate party to a surrogacy agreement resides in New York during the term of the agreement, or any medical procedure under the surrogacy agreement is performed in New York.

-Section 1402 states that surrogacy programs to which the newly-created article applies: must keep all funds paid by or on behalf of intended parents in separate, licensed escrow funds; may not be owned or managed by any attorney representing a party to a surrogacy agreement; may not make or receive paid referrals to attorneys representing any party to a surrogacy agreement, or any health care providers providing health services to any party to a surrogacy agreement; must be licensed to operate in New York State pursuant to regulations promulgated by the Department of Financial Services in consultation with the Department of Health; and must ensure that all potential parties to a surrogacy agreement are provided with written notice of the Surrogates' Bill of Rights enumerated in setions 581601 to 581-607 of the Family Court Act.

-Section 1403 directs the Department of Financial Services, in consultation with the Department of Health to promulgate regulations to implement the requirements of this newly-created article, and annually report to the Legislature regarding the practices of surrogacy programs and all business transactions related to surrogacy, along with recommendations for any necessary legislative changes.

Section 10 of the bill creates a new article 25-B of the Public Health Law entitled "Gestational Surrogacy.

-Section 2599-C requires the Commissioner of the Department of Health to promulgate regulations on the practice of gestational surrogacy, including establishing guidelines and procedures for obtaining fully informed consent from potential persons acting as surrogates, developing and distributing informational material relating to gestational surrogacy, and establishing a voluntary central tracking registry of persons acting as. surrogates.

Section 11 of the bill adds a new subdivision 4 to section 4365 of the Public Health Law to require the Commissioner of the Department of Health, in consultation with the Transplant Council, to promulgate regulations on the donation of ova (i.e. eggs), including establishing guidelines and procedures for obtaining fully informed consent from donors, developing and distributing informational material, relating to egg donation, and establishing a voluntary central tracking registry of egg donors.

Section 12 of the bill is the effective date.

JUSTIFICATION:

New York law has failed to keep pace with medical advances in assisted reproduction, causing uncertainty about who the legal parents of a child are upon birth. In many cases, the parentage of children created through donated sperm, eggs and embryos is unsettled or open to attack at the time of the child's birth and thereafter. Confusion or uncertainty regarding the parental rights of donors and intended parents (both genetic and non-genetic) who participate in the conception of the child through assisted reproduction is detrimental to the child, and secure family relations. Where children are born to a person acting as surrogate the parentage of the intended parents may not be recognized under current law. This is not only detrimental to the child; it also causes confusion in many critical situations. For example, a hospital does not know who must give consent when a newborn requires medical procedures. This bill will provide clear and decisive legal procedures to ensure that children born through assisted reproduction have secure and legally recognized parental relationships with their intended parents. The law will make it clear that donors do not have parental rights or obligations and that those rights and obli gations reside with the intended parents.

Importantly, this legislation lifts the existing ban on surrogacy contracts to permit enforceable surrogacy agreements and sets forth the criteria for such agreements. When all of the requirements set forth in the law are met, the intended parents can seek a "Judgment of Parentage" from a court, prior to the birth of the child, which becomes effective immediately upon birth. The requireMents are designed to ensure that all parties enter into the agreement on an equal footing and with full knowledge of their duties and obligations. For example, all parties must be represented by independent legal counsel, and the agreement may not limit the right of the person acting as surrogate to make their own healthcare decisions.

Because of existing New York laws, couples facing infertility and same-sex couples are forced to go out of state in order to have a child with the assistance of a person acting as surrogate. This is overly burdensome to the parents, who have often struggled for many years to have a child. Having an out-of-state person acting as surrogate may make it difficult, if not impossible, for the parents to fully participate in the pregnancy by attending doctor's appointments, etc. It also requires the participants to use out-of-state clinics and medical professionals despite the fact that New York is home to world-class medical facilities and fertility professionals.

New York appellate courts have repeatedly called upon the Legislature to act to provide much needed clarity to the essential question of who is a parent. The need to answer that call is more important today than ever as increasing numbers of children are being conceived and born through assisted reproduction. This bill clarifies the issue of who is a parent and establishes clear legal procedures which ensure that each child's relationship to his or her parent(s) is legally recognized from birth. As the New York Court of Appeals held in Brooke S.B. v Elizabeth A.C.O biology and adoption are not the only touchstones to determine parentage. This legislation provides a framework for determining the parentage of the large number of children unprotected under existing New York state law.

PRIOR LEGISLATIVE HISTORY:

S.0017-A of 2017-2018 (Hoylman): Died on 3rd Reading; Died in Judiciary

A.6959-A of 2017-2018 (Paulin): Died in Judiciary
S.2765 of 2015-2016 (Hoylman): Died in Children & Families
A.4319 of 2015-2016 (Paulin): Died in Judiciary
S.4617 of 2013-2014 (Hoylman): Died in Children & Families
A.6701 of 2013-2014 (Paulin): Died in Judiciary

FISCAL IMPLICATION:

To be determined.

EFFECTIVE DATE:
This act shall take effect on the one hundred twentieth day after it shall have become a law. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made on or before such date.

A01071 Text:

STATE OF NEW YORK

1071--C

2019-2020 Regular Sessions

IN ASSEMBLY

January 14, 2019

Introduced by M. of A. PAULIN, ZEBROWSKI, WEPRIN, GALEF, JAFFEE, OTIS, COOK, STIRPE, BENEDETTO, BRONSON, MOSLEY, ORTIZ, DINOWITZ, L. ROSENTHAL, STECK, SIMON, WOERNER, SOLAGES, CARROLL, DE LA ROSA, ROZIC, SIMOTAS, LAVINE, EPSTEIN, DICKENS, REYES, WALKER, RODRIGUEZ, STERN, PICHARDO, CRUZ, BLAKE, QUART, NIOU, SAYEGH -- Multi-Sponsored by -- M. of A. ENGLEBRIGHT, GOTTFRIED, PEOPLES-STOKES, THIELE -- read once and referred to the Committee on Judiciary -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- reported and referred to the Committee on Codes -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- again reported from said committee with amendments, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the family court act, in relation to judgments of parentage of children conceived through assisted reproduction or pursuant to surrogacy agreements; to amend the domestic relations law, in relation to restricting genetic surrogate parenting contracts; to amend the public health law, in relation to voluntary acknowledgments of parentage, gestational surrogacy and regulations concerning ova donation; to amend the general business law, in relation to the regulation of surrogacy programs; and to repeal section 73 of the domestic relations law, relating to legitimacy of children born by artificial insemination

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The family court act is amended by adding a new article 5-C to read as follows:

ARTICLE 5-C

JUDGMENTS OF PARENTAGE OF CHILDREN CONCEIVED THROUGH ASSISTED REPRODUCTION OR PURSUANT TO SURROGACY AGREEMENTS

EXPLANATION--Matter in ***italics*** (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD01279-28-9

5. Payment to donors and persons acting as surrogates (581-501 - 581-502)
6. Surrogates' bill of rights (581-601 - 581-607)
7. Miscellaneous provisions (581-701 - 581-704)

PART 1
GENERAL PROVISIONS

Section 581-101. Purpose.
581-102. Definitions.

§ 581-101. Purpose. The purpose of this article is to legally establish a child's relationship to his or her parents where the child is conceived through assisted reproduction except for children born to a person acting as surrogate who contributed the gametes used in conception. No fertilized egg, embryo or fetus shall have any independent rights under the laws of this state, nor shall any fertilized egg, embryo or fetus be viewed as a child under the laws of this state.

§ 581-102. Definitions. (a) "Assisted reproduction" means a method of causing pregnancy other than sexual intercourse and includes but is not limited to:

1. intrauterine or vaginal insemination;
2. donation of gametes;
3. donation of embryos;
4. in vitro fertilization and transfer of embryos; and
5. intracytoplasmic sperm injection.

(b) "Child" means a born individual of any age whose parentage may be determined under this act or other law.

(c) "Compensation" means payment of any valuable consideration in excess of reasonable medical and ancillary costs.

(d) "Donor" means an individual who does not intend to be a parent who produces gametes and provides them to another person, other than the individual's spouse, for use in assisted reproduction. The term does not include a person who is a parent under part three of this article. Donor also includes an individual who had dispositional control of an embryo who then transfers dispositional control and relinquishes all present and future parental and inheritance rights and obligations to a resulting child.

(e) "Embryo" means a cell or group of cells containing a diploid complement of chromosomes or group of such cells, not a gamete or gametes, that has the potential to develop into a live born human being if transferred into the body of a person under conditions in which gestation may be reasonably expected to occur.

(f) "Embryo transfer" means all medical and laboratory procedures that are necessary to effectuate the transfer of an embryo into the uterine cavity.

(g) "Gamete" means a cell containing a haploid complement of DNA that has the potential to form an embryo when combined with another gamete. Sperm and eggs are gametes.

(h) "Surrogacy agreement" is an agreement between at least one intended parent and a person acting as surrogate intended to result in a live birth where the child will be the legal child of the intended parents.

(i) "Person acting as surrogate" means an adult person, not an intended parent, who enters into a surrogacy agreement to bear a child who will be the legal child of the intended parent or parents so long as the person acting as surrogate has not provided the egg used to conceive the resulting child.

(j) "Health care practitioner" means an individual licensed or certified under title eight of the education law acting within his or her scope of practice.

(k) "Intended parent" is an individual who manifests the intent to be legally bound as the parent of a child resulting from assisted reproduction or a surrogacy agreement provided he or she meets the requirements of this article.

(l) "In vitro fertilization" means the formation of a human embryo outside the human body.

(m) "Parent" means an individual who has established a parent-child relationship under this act or other law.

(n) "Participant" is an individual who either: provides a gamete that is used in assisted reproduction, is an intended parent, is a person acting as surrogate, or is the spouse of an intended parent or person acting as surrogate.

(o) "Record" means information inscribed in a tangible medium or stored in an electronic or other medium that is retrievable in perceivable form.

(p) "Retrieval" means the procurement of eggs or sperm from a gamete provider.

(q) "Spouse" means an individual married to another, or who has a legal relationship entered into under the laws of the United States or of any state, local or foreign jurisdiction, which is substantially equivalent to a marriage, including a civil union or domestic partnership.

(r) "State" means a state of the United States, the District of Columbia, Puerto Rico, the United States Virgin Islands, or any territory or insular possession subject to the jurisdiction of the United States.

(s) "Transfer" means the placement of an embryo or gametes into the body of a person with the intent to achieve pregnancy and live birth.

PART 2

JUDGMENT OF PARENTAGE

Section 581-201. Judgment of parentage.

581-202. Proceeding for judgment of parentage of a child conceived through assisted reproduction.

581-203. Proceeding for judgment of parentage of a child conceived pursuant to a surrogacy agreement.

581-204. Judgment of parentage for intended parents who are spouses.

581-205. Inspection of records.

581-206. Jurisdiction, and exclusive continuing jurisdiction.

§ 581-201. Judgment of parentage. (a) A civil proceeding may be maintained to adjudicate the parentage of a child under the circumstances set forth in this article. This proceeding is governed by the civil practice law and rules.

(b) A judgment of parentage may be issued prior to birth but shall not become effective until the birth of the child.

(c) A petition for a judgment of parentage or nonparentage of a child conceived through assisted reproduction may be initiated by (1) a child, or (2) a parent, or (3) a participant, or (4) a person with a claim to parentage, or (5) the support/enforcement agency or other governmental agency authorized by other law, or (6) a representative authorized by law to act for an individual who would otherwise be entitled to maintain a proceeding but who is deceased, incapacitated, or a minor, in order to legally establish the child-parent relationship of either a child born

through assisted reproduction under part three of this article or a child born pursuant to a surrogacy agreement under part four of this article.

§ 581-202. Proceeding for judgment of parentage of a child conceived through assisted reproduction. (a) A proceeding for a judgment of parentage with respect to a child conceived through assisted reproduction may be commenced:

(1) if the intended parent resides in New York state, in the county where the intended parent resides any time after pregnancy is achieved or in the county where the child was born or resides; or

(2) if the intended parent and child do not reside in New York state, up to ninety days after the birth of the child in the county where the child was born.

(b) The petition for a judgment of parentage must be verified.

(c) Where a petition includes the following statements, the court must adjudicate any intended parent to be the parent of the child:

(1) a statement that an intended parent has been a resident of the state for at least ninety days or if an intended parent is not a New York state resident, that the child will be or was born in the state within ninety days of filing; and

(2) a statement from the gestating intended parent that the gestating intended parent became pregnant as a result of assisted reproduction; and

(3) in cases where there is a non-gestating intended parent, a statement from the gestating intended parent and non-gestating intended parent that the non-gestating intended parent consented to assisted reproduction pursuant to section 581-304 of this article; and

(4) proof of any donor's donative intent.

(d) The following shall be deemed sufficient proof of a donor's donative intent for purposes of this section:

(1) in the case of an anonymous donor or where gametes or embryos have previously been relinquished to a gamete or embryo storage facility or in the presence of a health care practitioner, a statement from the gamete or embryo storage facility or health care practitioner that the donor does not retain any parental or proprietary interest in the gametes or embryos; or

(2) in the case of a donation from a known donor, either: a. a record from the gamete or embryo donor acknowledging the donation and confirming that the donor has no parental or proprietary interest in the gametes or embryos. The record shall be signed by the gestating intended parent and the gamete or embryo donor. The record may be, but is not required to be, signed:

(i) before a notary public, or

(ii) before two witnesses who are not the intended parents, or

(iii) before a health care practitioner; or

b. clear and convincing evidence that the gamete or embryo donor agreed, prior to conception, with the gestating parent that the donor has no parental or proprietary interest in the gametes or embryos.

(3) In the absence of evidence pursuant to paragraph two of this subdivision, notice shall be given to the donor at least twenty days prior to the proceeding by delivery of a copy of the petition and notice. Upon a showing to the court, by affidavit or otherwise, on or before the date of the proceeding or within such further time as the court may allow, that personal service cannot be effected at the donor's last known address with reasonable effort, notice may be given, without prior court order therefore, at least twenty days prior to the proceed-

ing by registered or certified mail directed to the donor's last known address. Notice by publication shall not be required to be given to a donor entitled to notice pursuant to the provisions of this section.

(4) Notwithstanding the above, where sperm is provided under the supervision of a health care practitioner to someone other than the sperm provider's intimate partner or spouse without a record of the sperm provider's intent to parent, the sperm provider is presumed to be a donor and notice is not required.

(e) In cases not covered by subdivision (c) of this section, the court shall adjudicate the parentage of the child consistent with part three of this article.

(f) Where the requirements of subdivision (c) of this section are met or where the court finds the intended parent to be a parent under subdivision (e) of this section, the court shall issue a judgment of parentage:

(1) declaring, that upon the birth of the child, the intended parent is the legal parent of the child; and

(2) ordering the intended parent to assume responsibility for the maintenance and support of the child immediately upon the birth of the child; and

(3) if there is a donor, ordering that the donor is not a parent of the child; and

(4) ordering that upon the birth of the child, a copy of the judgment of parentage be served on the (i) department of health or New York city department of mental health and hygiene, or (ii) registrar of births in the hospital where the child is born and directing that the hospital report the parentage of the child to the appropriate department of health in conformity with the court order. If an original birth certificate has already issued, the court shall issue an order directing the appropriate department of health to amend the birth certificate in an expedited manner and seal the previously issued birth certificate.

§ 581-203. Proceeding for judgment of parentage of a child conceived pursuant to a surrogacy agreement. (a) The proceeding may be commenced at any time after the surrogacy agreement has been executed by all of the parties. Any party to the surrogacy agreement not joining in the petition must be served with notice of the proceeding.

(b) The petition for a judgment of parentage must be verified and include the following:

(1) a statement that the person acting as surrogate or at least one of the intended parents has been a resident of the state for at least ninety days at the time the surrogacy agreement was executed; and

(2) a certification from the attorney representing the intended parent or parents and the attorney representing the person acting as surrogate that the requirements of part four of this article have been met; and

(3) a statement from all parties to the surrogacy agreement that they entered into the surrogacy agreement knowingly and voluntarily.

(c) Where a petition satisfies subdivision (b) of this section the court shall issue a judgment of parentage, without additional proceedings or documentation:

(1) declaring, that upon the birth of the child born during the term of the surrogacy agreement, the intended parent or parents is the legal parent or parents of the child; and

(2) declaring, that upon the birth of the child born during the term of the surrogacy agreement, the person acting as surrogate, and the spouse of the person acting as surrogate, if any, is not the legal parent of the child; and

(3) ordering the person acting as surrogate and the spouse of the person acting as surrogate, if any, to transfer the child to the intended parent or parents if this has not already occurred; and

(4) ordering the intended parent or parents to assume responsibility for the maintenance and support of the child immediately upon the birth of the child; and

(5) ordering that upon the birth of the child, a copy of the judgment of parentage be served on the (i) department of health or New York city department of mental health and hygiene, or (ii) registrar of births in the hospital where the child is born and directing that the hospital report the parentage of the child to the appropriate department of health in conformity with the court order. If an original birth certificate has already issued, the court shall issue an order directing the appropriate department of health to amend the birth certificate in an expedited manner and seal the previously issued birth certificate.

(d) In the event the certification required by paragraph two of subdivision (b) of this section cannot be made because of a technical or non-material deviation from the requirements of this article; the court may nevertheless enforce the agreement and issue a judgment of parentage if the court determines the agreement is in substantial compliance with the requirements of this article.

§ 581-204. Judgment of parentage for intended parents who are spouses. Notwithstanding or without limitation on presumptions of parentage that apply, a judgment of parentage may be obtained under this part by intended parents who are each other's spouse.

§ 581-205. Inspection of records. Court records relating to proceedings under this article shall be sealed. The parties to the proceeding and the child shall have the right to inspect the entire court record, including, but not limited to, the name of the person acting as surrogate and any known donors.

§ 581-206. Jurisdiction, and exclusive continuing jurisdiction. (a) Proceedings pursuant to this article may be instituted in the supreme or family court.

(b) Subject to the jurisdictional standards of section seventy-six of the domestic relations law, the court conducting a proceeding under this article has exclusive, continuing jurisdiction of all matters relating to the determination of parentage until the child attains the age of one hundred eighty days.

PART 3

CHILD OF ASSISTED REPRODUCTION

§ 581-301. Scope of article. This article does not apply to the birth of a child conceived by means of sexual intercourse.

§ 581-302. Status of donor. A donor is not a parent of a child conceived by means of assisted reproduction.

§ 581-303. Parentage of child of assisted reproduction. (a) An individual who provides gametes for, or who consents to, assisted reproduction with the intent to be a parent of the child with the consent of the gestating parent as provided in section 581-304 of this part, is a parent of the resulting child for all legal purposes.

(b) The court shall issue a judgment of parentage pursuant to this article upon application by any participant.

§ 581-304. Consent to assisted reproduction. (a) Where the intended parent who gives birth to a child by means of assisted reproduction is a spouse, the consent of both spouses to the assisted reproduction is presumed and neither spouse may challenge the parentage of the child, except as provided in section 581-305 of this part.

(b) Where the intended parent who gives birth to a child by means of assisted reproduction is not a spouse, the consent to the assisted reproduction must be in a record in such a manner as to indicate the mutual agreement of the intended parents to conceive and parent a child together.

(c) The absence of a record described in subdivision (b) of this section shall not preclude a finding that such consent existed if the court finds by clear and convincing evidence that at the time of the assisted reproduction the intended parents agreed to conceive and parent the child together.

§ 581-305. Limitation on spouses' dispute of parentage of child of assisted reproduction. (a) Except as otherwise provided in subdivision (b) of this section, neither spouse may challenge the presumption of parentage of the child unless:

(1) within two years after learning of the birth of the child a proceeding is commenced to adjudicate parentage; and

(2) the court finds by clear and convincing evidence that either spouse did not consent for the non-gestating spouse to be a parent of the child.

(b) A proceeding for a judgment of parentage may be maintained at any time if the court finds by clear and convincing evidence that:

(1) the spouse did not consent to assisted reproduction by the individual who gave birth; and

(2) the spouse and the individual who gave birth have not cohabited since the spouse knew or had reason to know of the pregnancy; and

(3) the spouse never openly held out the child as his or her own.

(c) The limitation provided in this section applies to a spousal relationship that has been declared invalid after assisted reproduction or artificial insemination.

§ 581-306. Effect of embryo disposition agreement between intended parents which transfers legal rights and dispositional control to one intended parent. (a) An embryo disposition agreement between intended parents with joint dispositional control of an embryo shall be binding under the following circumstances:

(1) it is in writing;

(2) each intended parent had the advice of independent legal counsel prior to its execution; and

(3) where the intended parents are married, transfer of legal rights and dispositional control occurs only upon divorce.

(b) The intended parent who transfers legal rights and dispositional control of the embryo is not a parent of any child conceived from the embryo unless the agreement states that he or she consents to be a parent.

(c) If the intended parent transferring legal rights and dispositional control consents to be a parent, he or she may withdraw his or her consent to be a parent upon written notice to the embryo storage facility and to the other intended parent prior to transfer of the embryo. If he or she timely withdraws consent to be a parent he or she is not a parent for any purpose including support obligations but the embryo transfer may still proceed.

(d) An embryo disposition agreement or advance directive that is not in compliance with subdivision (a) of this section may still be found to be enforceable by the court after balancing the respective interests of the parties except that the intended parent who divested him or herself of legal rights and dispositional control may not be declared to be a parent for any purpose without his or her consent. The parent awarded legal rights and dispositional control of the embryos shall, in this instance, be declared to be the only parent of the child.

§ 581-307. Effect of death of intended parent. If an individual who consented in a record to be a parent by assisted reproduction dies before the transfer of eggs, sperm, or embryos, the deceased individual is not a parent of the resulting child unless the deceased individual consented in a signed record that if assisted reproduction were to occur after death, the deceased individual would be a parent of the child, provided that the record complies with the estates, powers and trusts law.

PART 4

SURROGACY AGREEMENT

Section 581-401. Surrogacy agreement authorized.
581-402. Eligibility to enter surrogacy agreement.
581-403. Requirements of surrogacy agreement.
581-404. Surrogacy agreement: effect of subsequent spousal relationship.
581-405. Termination of surrogacy agreement.
581-406. Parentage under compliant surrogacy agreement.
581-407. Insufficient surrogacy agreement.
581-408. Absence of surrogacy agreement.
581-409. Dispute as to surrogacy agreement.

§ 581-401. Surrogacy agreement authorized. (a) If eligible under this article to enter into a surrogacy agreement, a person acting as surrogate, the spouse of the person acting as surrogate, if applicable, and the intended parent or parents may enter into a surrogacy agreement which will be enforceable provided the surrogacy agreement meets the requirements of this article.

(b) A surrogacy agreement shall not apply to the birth of a child conceived by means of sexual intercourse.

(c) A surrogacy agreement may provide for payment of compensation under part five of this article.

§ 581-402. Eligibility to enter surrogacy agreement. (a) A person acting as surrogate shall be eligible to enter into an enforceable surrogacy agreement under this article if the person acting as surrogate has met the following requirements at the time the surrogacy agreement is executed:

(1) the person acting as surrogate is at least twenty-one years of age; and

(2) the person acting as surrogate is a United States citizen or a permanent lawful resident;

(3) the person acting as surrogate has not provided the egg used to conceive the resulting child; and

(4) the person acting as surrogate has completed a medical evaluation with a health care practitioner relating to the anticipated pregnancy; and

(5) the person acting as surrogate, and the spouse of the person acting as surrogate, if applicable, have been represented throughout the contractual process and the duration of the contract and its execution by independent legal counsel of their own choosing which shall be paid for by the intended parent or parents except that a person acting as surrogate who is receiving no compensation may waive the right to have the intended parent or parents pay the fee for such legal counsel. Where the intended parent or parents are paying for the independent legal counsel of the person acting as surrogate, and the spouse of the person acting as surrogate, if applicable, a separate retainer agreement shall be prepared clearly stating that such legal counsel will only represent the person acting as surrogate and the spouse of the person acting as surrogate, if applicable, in all matters pertaining to the surrogacy agreement, that such legal counsel will not offer legal advice to any other parties to the surrogacy agreement, and that the attorney-client relationship lies with the person acting as surrogate and the spouse of the person acting as surrogate, if applicable; and

(6) the person acting as surrogate has, or the surrogacy agreement stipulates that prior to the embryo transfer, the person acting as surrogate will obtain a health insurance policy that covers major medical treatments and hospitalization, and the health insurance policy has a term that extends throughout the duration of the expected pregnancy and for twenty-six weeks after the birth of the child; the policy shall be paid for, whether directly or through reimbursement or other means, by the intended parent or parents on behalf of the person acting as surrogate pursuant to the surrogacy agreement, except that a person acting as surrogate who is receiving no compensation may waive the right to have the intended parent or parents pay for the health insurance policy. The intended parent or parents shall also pay for or reimburse the person acting as surrogate for all co-payments, deductibles and any other out-of-pocket medical costs associated with pregnancy, that accrue through twelve weeks after the birth of the child or termination of the pregnancy, except that such responsibility shall be extended for up to six months after the birth of the child or termination of the pregnancy in the event a medical complication related to the pregnancy is diagnosed within twelve weeks after the birth of the child or termination or the pregnancy. A person acting as surrogate who is receiving no compensation may waive the right to have the intended parent or parents make such payments or reimbursements.

(b) The intended parent or parents shall be eligible to enter into an enforceable surrogacy agreement under this article if he, she or they have met the following requirements at the time the surrogacy agreement was executed:

(1) at least one intended parent is a United States citizen or a permanent lawful resident;

(2) the intended parent or parents has been represented throughout the contractual process and the duration of the contract and its execution by independent legal counsel of his, her or their own choosing; and

(3) he or she is an adult person who is not in a spousal relationship, or adult spouses together, or any two adults who are intimate partners together, except an adult in a spousal relationship is eligible to enter into an enforceable surrogacy agreement without his or her spouse if:

(i) they are living separate and apart pursuant to a decree or judgment of separation or pursuant to a written agreement of separation subscribed by the parties thereto and acknowledged or proved in the form required to entitle a deed to be recorded; or

(ii) they have been living separate and apart for at least three years prior to execution of the surrogacy agreement.

(4) where the spouse of an intended parent is not a required party to the agreement, the spouse is not an intended parent and shall not have rights or obligations to the child.

§ 581-403. Requirements of surrogacy agreement. A surrogacy agreement shall be deemed to have satisfied the requirements of this article and be enforceable if it meets the following requirements:

(a) it shall be in a signed record verified by:

(1) each intended parent, and

(2) the person acting as surrogate, and the spouse of the person acting as surrogate, if any, unless:

(i) the person acting as surrogate and the spouse of the person acting as surrogate are living separate and apart pursuant to a decree or judgment of separation or pursuant to a written agreement of separation subscribed by the parties thereto and acknowledged or proved in the form required to entitle a deed to be recorded; or

(ii) have been living separate and apart for at least three years prior to execution of the surrogacy agreement; and

(b) it shall be executed prior to the embryo transfer; and

(c) it shall be executed by a person acting as surrogate meeting the eligibility requirements of subdivision (a) of section 581-402 of this part and by the spouse of the person acting as surrogate, unless the signature of the spouse of the person acting as surrogate is not required as set forth in this section; and

(d) it shall be executed by intended parent or parents who met the eligibility requirements of subdivision (b) of section 581-402 of this part; and

(e) the person acting as surrogate and the spouse of the person acting as surrogate, if applicable, and the intended parent or parents shall have been represented throughout the contractual process and the duration of the contract and its execution by separate, independent legal counsel of their own choosing; and

(f) if the surrogacy agreement provides for the payment of compensation to the person acting as surrogate, those funds shall have been placed in escrow with an independent escrow agent prior to the person acting as surrogate commencing with any medical procedure other than medical evaluations necessary to determine the person acting as surrogate's eligibility; and

(g) the surrogacy agreement must include information disclosing how the intended parent or parents will cover the medical expenses of the person acting as surrogate and the child. If health care coverage is used to cover the medical expenses, the disclosure shall include a review of the health care policy provisions related to coverage for the person acting as surrogate's pregnancy, including any possible liability of the person acting as surrogate's third-party liability liens or other insurance coverage, and any notice requirements that could affect coverage or liability of the person acting as surrogate.

(h) the surrogacy agreement must comply with all of the following terms:

(1) As to the person acting as surrogate and the spouse of the person acting as surrogate, if applicable:

(i) the person acting as surrogate agrees to undergo embryo transfer and attempt to carry and give birth to the child; and

(ii) the person acting as surrogate and the spouse of the person acting as surrogate, if applicable, agree to surrender custody of all resulting children to the intended parent or parents immediately upon birth; and

(iii) the surrogacy agreement shall include the name of the attorney representing the person acting as surrogate and, if applicable, the spouse of the person acting as surrogate; and

(iv) the surrogacy agreement must permit the person acting as surrogate to make all health and welfare decisions regarding themself and their pregnancy including but not limited to, whether to consent to a cesarean section or multiple embryo transfer, and notwithstanding any other provisions in this chapter, provisions in the agreement to the contrary are void and unenforceable. This article does not diminish the right of the person acting as surrogate to terminate a pregnancy; and

(v) the surrogacy agreement must permit the person acting as a surrogate to utilize the services of a health care practitioner of the person's choosing; and

(vi) the surrogacy agreement must not limit the right of the person acting as surrogate to terminate or continue the pregnancy or reduce or retain the number of fetuses or embryos the person is carrying; and

(vii) the surrogacy agreement must provide that, upon request, the intended parent or parents have or will procure and pay for a life insurance policy for the person acting as surrogate; the person acting as surrogate may designate the beneficiary of the person's choosing; and

(viii) the surrogacy agreement shall provide for the right of the person acting as surrogate, upon request, to obtain counseling to address issues resulting from the person's participation in the surrogacy agreement. The cost of that counseling shall be paid by the intended parent or parents.

(2) As to the intended parent or parents:

(i) the intended parent or parents agree to accept custody of all resulting children immediately upon birth regardless of number, gender, or mental or physical condition; and

(ii) the intended parent or parents agree to assume responsibility for the support of all resulting children immediately upon birth; and

(iii) the surrogacy agreement shall include the name of the attorney representing the intended parent or parents; and

(iv) the surrogacy agreement shall provide that the rights and obligations of the intended parent or parents under the surrogacy agreement are not assignable; and

(v) the intended parent or parents agree to execute a will, prior to the embryo transfer, designating a guardian for all resulting children who is authorized to perform the intended parent's or parents' obligations pursuant to the surrogacy agreement.

§ 581-404. Surrogacy agreement: effect of subsequent spousal relationship. (a) After the execution of a surrogacy agreement under this article, the subsequent spousal relationship of the person acting as surrogate does not affect the validity of a surrogacy agreement, the consent of the spouse of the person acting as surrogate to the agreement shall not be required, and the spouse of the person acting as surrogate shall not be the presumed parent of any resulting children.

(b) The subsequent separation or divorce of the intended parents does not affect the rights, duties and responsibilities of the intended parents as outlined in the surrogacy agreement.

§ 581-405. Termination of surrogacy agreement. After the execution of a surrogacy agreement but before the person acting as surrogate becomes pregnant by means of assisted reproduction, the person acting as surrogate, the spouse of the person acting as surrogate, if applicable, or any intended parent may terminate the surrogacy agreement by giving notice of termination in a record to all other parties. Upon proper termination of the surrogacy agreement the parties are released from all obligations recited in the surrogacy agreement except that the intended parent or parents remains responsible for all expenses that are reimbursable under the agreement which have been incurred by the person acting as surrogate through the date of termination. Unless the agreement provides otherwise, the person acting as surrogate is entitled to keep all payments received and obtain all payments to which the person is entitled up until the date of termination. Neither a person acting as surrogate nor the spouse of the person acting as surrogate, if any, is liable to the intended parent or parents for terminating a surrogacy agreement as provided in this section.

§ 581-406. Parentage under compliant surrogacy agreement. Upon the birth of a child conceived by assisted reproduction under a surrogacy agreement that complies with this part, each intended parent is, by operation of law, a parent of the child and neither the person acting as a surrogate nor the person's spouse, if any, is a parent of the child.

§ 581-407. Insufficient surrogacy agreement. If a surrogacy agreement does not meet the material requirements of this article, the agreement is not enforceable and the court shall determine parentage based on the intent of the parties, taking into account the best interests of the child. An intended parent's absence of genetic connection to the child is not a sufficient basis to deny that individual a judgment of legal parentage.

§ 581-408. Absence of surrogacy agreement. Where there is no surrogacy agreement, the parentage of the child will be determined based on other laws of this state.

§ 581-409. Dispute as to surrogacy agreement. (a) Any dispute which is related to a surrogacy agreement other than disputes as to parentage shall be resolved by the supreme court, which shall determine the respective rights and obligations of the parties.

(b) Except as expressly provided in the surrogacy agreement, the intended parent or parents and the person acting as surrogate shall be entitled to all remedies available at law or equity in any dispute related to the surrogacy agreement.

(c) There shall be no specific performance remedy available for a breach by the person acting as surrogate of a surrogacy agreement term that requires the person acting as surrogate to be impregnated or to terminate or continue the pregnancy or to reduce or retain the number of fetuses or embryos the person acting as surrogate is carrying.

PART 5

PAYMENT TO DONORS AND PERSONS ACTING AS SURROGATES

§ 581-501. Reimbursement. (a) A donor who has entered into a valid agreement to be a donor may receive reimbursement from an intended parent or parents for economic losses incurred in connection with the donation which result from the retrieval or storage of gametes or embryos.

(b) Premiums paid for insurance against economic losses directly resulting from the retrieval or storage of gametes or embryos for donation may be reimbursed.

§ 581-502. Compensation. (a) Compensation may be paid to a donor or person acting as surrogate based on medical risks, physical discomfort, inconvenience and the responsibilities they are undertaking in connection with their participation in the assisted reproduction. Under no circumstances may compensation be paid to purchase gametes or embryos or for the relinquishment of a parental interest in a child.

(b) The compensation, if any, paid to a donor or person acting as surrogate must be reasonable and negotiated in good faith between the parties, and said payments to a person acting as surrogate shall not exceed the duration of the pregnancy and recuperative period of up to eight weeks after the birth of any resulting children.

(c) Compensation may not be conditioned upon the purported quality or genome-related traits of the gametes or embryos.

(d) Compensation may not be conditioned on actual genotypic or phenotypic characteristics of the donor or of any resulting children.

PART 6

SURROGATES' BILL OF RIGHTS

Section 581-601. Applicability.

581-602. Health and welfare decisions.

581-603. Independent legal counsel.

581-604. Health insurance and medical costs.

581-605. Counseling.

581-606. Life insurance.

581-607. Termination of surrogacy agreement.

§ 581-601. Applicability. The rights enumerated in this part shall apply to any person acting as surrogate in this state, notwithstanding any surrogacy agreement, judgment of parentage, memorandum of understanding, verbal agreement or contract to the contrary. Except as otherwise provided by law, any written or verbal agreement purporting to waive or limit any of the rights in this part is void as against public policy. The rights enumerated in this part are not exclusive, and are in addition to any other rights provided by law, regulation, or a surrogacy agreement that meets the requirements of this article.

§ 581-602. Health and welfare decisions. A person acting as surrogate has the right to make all health and welfare decisions regarding themself and their pregnancy, including but not limited to whether to consent to a cesarean section or multiple embryo transfer, to utilize the services of a health care practitioner of their choosing, whether to terminate or continue the pregnancy, and whether to reduce or retain the number of fetuses or embryos they are carrying.

§ 581-603. Independent legal counsel. A person acting as surrogate has the right to be represented throughout the contractual process and the duration of the surrogacy agreement and its execution by independent legal counsel of their own choosing, to be paid for by the intended parent or parents.

§ 581-604. Health insurance and medical costs. A person acting as surrogate has the right to a health insurance policy that covers major medical treatments and hospitalization for a term that extends throughout the duration of the expected pregnancy and for twelve weeks after the birth of the child, to be paid for by the intended parent or parents. The intended parent or parents shall also pay for or reimburse the person acting as surrogate for all co-payments, deductibles and any

other out-of-pocket medical costs associated with pregnancy that accrue through twelve weeks after the birth of the child or termination of the pregnancy, except that such responsibility shall be extended for up to six months after the birth of the child or termination of the pregnancy in the event a medical complication related to the pregnancy is diagnosed within twelve weeks after the birth of the child or termination of the pregnancy.

§ 581-605. Counseling. A person acting as surrogate has the right to obtain counseling to address issues resulting from their participation in a surrogacy agreement, to be paid for by the intended parent or parents.

§ 581-606. Life insurance. A person acting as surrogate has the right to be provided with a life insurance policy for the duration of the surrogacy agreement, with a beneficiary or beneficiaries of their choosing, to be paid for by the intended parent or parents.

§ 581-607. Termination of surrogacy agreement. A person acting as surrogate has the right to terminate a surrogacy agreement prior to becoming pregnant by means of assisted reproduction pursuant to section 581-405 of this article.

PART 7

MISCELLANEOUS PROVISIONS

§ 581-701. Remedial. This legislation is hereby declared to be a remedial statute and is to be construed liberally to secure the beneficial interests and purposes thereof for the best interests of the child.

§ 581-702. Severability. The invalidation of any part of this legislation by a court of competent jurisdiction shall not result in the invalidation of any other part.

§ 581-703. Parent under section seventy of the domestic relations law. The term "parent" in section seventy of the domestic relations law shall include a person established to be a parent under this article or any other relevant law.

§ 581-704. Interpretation. Unless the context indicates otherwise, words importing the singular include and apply to several persons, parties, or things; words importing the plural include the singular.

§ 2. Section 73 of the domestic relations law is REPEALED.

§ 3. Section 121 of the domestic relations law, as added by chapter 308 of the laws of 1992, is amended to read as follows:

§ 121. Definitions. When used in this article, unless the context or subject matter manifestly requires a different interpretation:

1.[~~"Birth mother"~~] **"Genetic surrogate"** shall mean a [~~woman~~] **person** who gives birth to a child **who is the person's genetic child** pursuant to a **genetic** surrogate parenting [~~contract~~] **agreement**.

2. [~~"Genetic father" shall mean a man who provides sperm for the birth of a child born pursuant to a surrogate parenting contract.~~

~~3. "Genetic mother" shall mean a woman who provides an ovum for the birth of a child born pursuant to a surrogate parenting contract.~~

~~4. "Surrogate parenting contract"~~] **"Genetic surrogate parenting agreement"** shall mean any agreement, oral or written, in which:

(a) a [~~woman~~] **genetic surrogate** agrees either to be inseminated with the sperm of a [~~man~~] **person** who is not [~~her husband~~] **their spouse** or to

be impregnated with an embryo that is the product of [~~an~~] **the genetic surrogate's** ovum fertilized with the sperm of a [~~man~~] **person** who is not [~~her husband~~] **their spouse**; and

(b) the [~~woman~~] **genetic surrogate** agrees to, or intends to, surrender or consent to the adoption of the child born as a result of such insemination or impregnation.

§ 4. Section 122 of the domestic relations law, as added by chapter 308 of the laws of 1992, is amended to read as follows:

§ 122. Public policy. [~~Surrogate~~] **Genetic surrogate** parenting [~~contracts~~] **agreements** are hereby declared contrary to the public policy of this state, and are void and unenforceable.

§ 5. Section 123 of the domestic relations law, as added by chapter 308 of the laws of 1992, is amended to read as follows:

§ 123. Prohibitions and penalties. [~~1.~~] No person or other entity shall knowingly request, accept, receive, pay or give any fee, compensation or other remuneration, directly or indirectly, in connection with any **genetic** surrogate parenting [~~contract~~] **agreement**, or induce, arrange or otherwise assist in arranging a **genetic** surrogate parenting [~~contract~~] **agreement** for a fee, compensation or other remuneration, except for:

(a) payments in connection with the adoption of a child permitted by subdivision six of section three hundred seventy-four of the social services law and disclosed pursuant to subdivision eight of section one hundred fifteen of this chapter; or

(b) payments for reasonable and actual medical fees and hospital expenses for artificial insemination or in vitro fertilization services incurred by the [~~mother~~] **genetic surrogate** in connection with the birth of the child.

~~[2. (a) A birth mother or her husband, a genetic father and his wife, and, if the genetic mother is not the birth mother, the genetic mother and her husband who violate this section shall be subject to a civil penalty not to exceed five hundred dollars.~~

~~(b) Any other person or entity who or which induces, arranges or otherwise assists in the formation of a surrogate parenting contract for a fee, compensation or other remuneration or otherwise violates this section shall be subject to a civil penalty not to exceed ten thousand dollars and forfeiture to the state of any such fee, compensation or remuneration in accordance with the provisions of subdivision (a) of section seven thousand two hundred one of the civil practice law and rules, for the first such offense. Any person or entity who or which induces, arranges or otherwise assists in the formation of a surrogate parenting contract for a fee, compensation or other remuneration or otherwise violates this section, after having been once subject to a civil penalty for violating this section, shall be guilty of a felony.~~]

§ 6. Section 124 of the domestic relations law, as added by chapter 308 of the laws of 1992, is amended to read as follows:

§ 124. Proceedings regarding parental rights, status or obligations. In any action or proceeding involving a dispute between the [~~birth mother~~] **genetic surrogate** and [~~(i) the genetic father, (ii) the genetic mother, (iii) both the genetic father and genetic mother, or (iv) the parent or parents of the genetic father or genetic mother~~] **any party with a claim to legal parentage pursuant to a genetic surrogate parenting agreement**, regarding parental rights, status or obligations with respect to a child born pursuant to a **genetic** surrogate parenting [~~contract~~] **agreement**:

1. the court shall not consider the [~~birth mother's~~] **genetic surrogate's** participation in a **genetic** surrogate parenting [~~contract~~] **agreement** as adverse to [~~her~~] **their** parental rights, status, or obligations; and

2. the court, having regard to the circumstances of the case and of the respective parties including the parties' relative ability to pay such fees and expenses, in its discretion and in the interests of justice, may award to either party reasonable and actual counsel fees and legal expenses incurred in connection with such action or proceeding. Such award may be made in the order or judgment by which the particular action or proceeding is finally determined, or by one or more orders from time to time before the final order or judgment, or by both such order or orders and the final order or judgment; provided, however, that in any dispute involving a [~~birth mother~~] **genetic surrogate** who has executed a valid surrender or consent to the adoption, nothing in this section shall empower a court to make any award that it would not otherwise be empowered to direct.

§ 7. Section 4135-b of the public health law, as added by chapter 59 of the laws of 1993, subdivisions 1 and 2 as amended by chapter 402 of the laws of 2013, and subdivision 3 as amended by chapter 170 of the laws of 1994, is amended to read as follows:

§ 4135-b. Voluntary acknowledgments of [~~paternity~~] **parentage**; child born out of wedlock. 1. (a) Immediately preceding or following the in-hospital birth of a child to an unmarried [~~woman~~] **person or to a person who gave birth to a child conceived through assisted reproduction**, the person in charge of such hospital or his or her designated representative shall provide to the [~~child's mother and~~] **unmarried person who gave birth to the child and the** putative father, if such father **is readily identifiable and available, or to the person who gave birth and the other intended parent of a child conceived through assisted reproduction if such person** is readily identifiable and available, the documents and written instructions necessary for such mother and putative [~~father~~] **persons** to complete an acknowledgment of [~~paternity~~] **parentage** witnessed by two persons not related to the signatory. Such acknowledgment, if signed by both parties, at any time following the birth of a child, shall be filed with the registrar at the same time at which the certificate of live birth is filed, if possible, or anytime thereafter. Nothing herein shall be deemed to require the person in charge of such hospital or his or her designee to seek out or otherwise locate a putative father **or intended parent of a child conceived through assisted reproduction** who is not readily identifiable or available.

(b) The following persons may sign an acknowledgment of parentage to establish the parentage of the child:

(i) An unmarried person who gave birth to the child and another person who is a genetic parent.

(ii) A married or unmarried person who gave birth to the child and another person who is an intended parent under section 581-303 of the family court act of a child conceived through assisted reproduction.

(c) An acknowledgment of parentage shall be in a record signed by the person who gave birth to the child and by either the genetic parent other than the person who gave birth to the child or a person who is a parent under section 581-303 of the family court act of the child conceived through assisted reproduction.

(d) An acknowledgment of parentage is void if, at the time of signing, any of the following are true:

(i) A person other than the person who gave birth to the child or a person seeking to establish parentage through an acknowledgment of parentage is a presumed parent of the child under section twenty-four of the domestic relations law;

(ii) A court has entered a judgment of parentage of the child;

(iii) Another person has signed a valid acknowledgment of parentage with regard to the child;

(iv) The child has a parent under section 581-303 of the family court act other than the signatories;

(v) The person seeking to establish parentage is a gamete donor under section 581-302 of the family court act;

(vi) The person seeking to establish parentage asserts that he or she is a parent under section twenty-four of the domestic relations law;

(vii) The person seeking to establish parentage asserts that he or she is a parent of a child conceived through assisted reproduction and the person is in fact, not a parent under section 581-303 of the family court act.

(e) The acknowledgment shall be executed on a form provided by the commissioner developed in consultation with the appropriate commissioner of the department of family assistance, which shall include the social security number of the [~~**mother**~~] **person who gave birth to the child** and of the [~~**putative father**~~] **acknowledged parent** and provide in plain language (i) a statement by the [~~**mother**~~] **person who gave birth to the child** consenting to the acknowledgment of [~~**paternity**~~] **parentage** and a statement that the [~~**putative father**~~] **acknowledged parent** is the only possible [~~**father**~~] **other genetic parent or that the acknowledged parent is an intended parent and the child was conceived through assisted reproduction**, (ii) a statement by the putative father**, if any,** that he is the biological father of the child, and (iii) a statement that the signing of the acknowledgment of [~~**paternity**~~] **parentage** by both parties shall have the same force and effect as an order of filiation entered after a court hearing by a court of competent jurisdiction, including an obligation to provide support for the child except that, only if filed with the registrar of the district in which the birth certificate has been filed, will the acknowledgment have such force and effect with respect to inheritance rights.

[~~**(b)**~~] **(f)** Prior to the execution of an acknowledgment of [~~**paternity**~~] **parentage**, the [~~**mother**~~] **person who gave birth to the child** and the [~~**putative father**~~] **other signatory** shall be provided orally, which may be through the use of audio or video equipment, and in writing with such information as is required pursuant to this section with respect to their rights and the consequences of signing a voluntary acknowledgment of [~~**paternity**~~] **parentage** including, but not limited to:

(i) that the signing of the acknowledgment of [~~**paternity**~~] **parentage** shall establish the [~~**paternity**~~] **parentage** of the child and shall have the same force and effect as an order of [~~**paternity**~~] **parentage** or filiation issued by a court of competent jurisdiction establishing the duty of both parties to provide support for the child;

(ii) that if such an acknowledgment is not made, the [~~**putative father**~~] **signatory other than the person who gave birth to the child** can be held liable for support only if the family court, after a hearing, makes an order declaring that the [~~**putative father**~~] **person** is the [~~**father**~~] **parent** of the child whereupon the court may make an order of support which may be retroactive to the birth of the child;

(iii) that if made a respondent in a proceeding to establish [~~**paternity**~~] **parentage** the [~~**putative father**~~] **signatory other than the person who**

gave birth to the child has a right to free legal representation if indigent;

(iv) that [~~**the putative father**~~] **an alleged genetic parent** has a right to a genetic marker test or to a DNA test when available;

(v) that by executing the acknowledgment, the [~~**putative father**~~] **alleged genetic parent** waives [~~**his**~~] **their** right to a hearing, to which [~~**he**~~] **they** would otherwise be entitled, on the issue of [~~**paternity**~~] **parentage**;

(vi) that a copy of the acknowledgment of [~~**paternity**~~] **parentage** shall be filed with the putative father registry pursuant to section three hundred seventy-two-c of the social services law, and that such filing may establish the child's right to inheritance from the putative father pursuant to clause (B) of subparagraph two of paragraph (a) of section 4-1.2 of the estates, powers and trusts law;

(vii) that, if such acknowledgment is filed with the registrar of the district in which the birth certificate has been filed, such acknowledgment will establish inheritance rights from the putative father **or the other intended parent of a child conceived through assisted reproduction** pursuant to clause (A) of subparagraph two of paragraph (a) of section 4-1.2 of the estates, powers and trusts law;

(viii) that no further judicial or administrative proceedings are required to ratify an unchallenged acknowledgment of [~~**paternity**~~] **parentage** provided, however, that:

(A) A signatory to an acknowledgment of [~~**paternity**~~] **parentage**, who had attained the age of eighteen at the time of execution of the acknowledgment, shall have the right to rescind the acknowledgment within the earlier of sixty days from the date of signing the acknowledgment or the date of an administrative or a judicial proceeding (including, but not limited to, a proceeding to establish a support order) relating to the child in which the signatory is a party, provided that the "date of an administrative or a judicial proceeding" shall be the date by which the respondent is required to answer the petition;

(B) A signatory to an acknowledgment of [~~**paternity**~~] **parentage**, who had not attained the age of eighteen at the time of execution of the acknowledgment, shall have the right to rescind the acknowledgment anytime up to sixty days after the signatory's attaining the age of eighteen years or sixty days after the date on which the respondent is required to answer a petition (including, but not limited to, a petition to establish a support order) relating to the child, whichever is earlier; provided, however, that the signatory must have been advised at such proceeding of his or her right to file a petition to vacate the acknowledgment within sixty days of the date of such proceeding;

(ix) that after the expiration of the time limits set forth in clauses (A) and (B) of subparagraph (viii) of this paragraph, any of the signatories may challenge the acknowledgment of [~~**paternity**~~] **parentage** in court only on the basis of fraud, duress, or material mistake of fact, with the burden of proof on the party challenging the voluntary acknowledgment;

(x) that the [~~**putative father and mother**~~] **person who gave birth to the child and the other signatory** may wish to consult with attorneys before executing the acknowledgment; and that they have the right to seek legal representation and supportive services including counseling regarding such acknowledgment;

(xi) that the acknowledgment of [~~**paternity**~~] **parentage** may be the basis for the [~~**putative father**~~] **signatory other than the person who gave birth to the child** establishing custody and visitation rights to the child and

for requiring the [~~putative father's~~] consent **of the signatory other than the person who gave birth to the child** prior to an adoption proceeding;

(xii) that the [~~mother's~~] refusal **of the person who gave birth to the child** to sign the acknowledgment shall not be deemed a failure to cooperate in establishing [~~paternity for~~] **parentage of** the child; and

(xiii) that the child may bear the last name of either parent, **or any combination thereof,** which name shall not affect the legal status of the child.

In addition, the governing body of such hospital shall insure that appropriate staff shall provide to the [~~child's mother and putative father~~] **person who gave birth to the child and the other signatory**, prior to the [~~mother's~~] discharge from the hospital **of the person who gave birth to the child**, the opportunity to speak with hospital staff to obtain clarifying information and answers to their questions about [~~paternity~~] **parentage** establishment, and shall also provide the telephone number of the local support collection unit.

[~~(c)~~] **(g)** Within ten days after receiving the certificate of birth, the registrar shall furnish without charge to each parent or guardian of the child or to the [~~mother~~] **person who gave birth** at the address designated by her for that purpose, a certified copy of the certificate of birth and, if applicable, a certified copy of the written acknowledgment of [~~paternity~~] **parentage**. If the [~~mother~~] **person who gave birth** is in receipt of child support enforcement services pursuant to title six-A of article three of the social services law, the registrar also shall furnish without charge a certified copy of the certificate of birth and, if applicable, a certified copy of the written acknowledgment of [~~paternity~~] **parentage** to the social services district of the county within which the [~~mother~~] **person who gave birth** resides.

2. (a) When a child's [~~paternity~~] **parentage** is acknowledged voluntarily pursuant to section one hundred eleven-k of the social services law, the social services official shall file the executed acknowledgment with the registrar of the district in which the birth occurred and in which the birth certificate has been filed.

(b) Where a child's [~~paternity~~] **parentage** has not been acknowledged voluntarily pursuant to paragraph (a) of subdivision one of this section or paragraph (a) of this subdivision, the [~~child's mother and the putative father~~] **person who gave birth to the child and the other signatory** may voluntarily acknowledge a child's [~~paternity~~] **parentage** pursuant to this paragraph by signing the acknowledgment of [~~paternity~~] **parentage**.

(c) A signatory to an acknowledgment of [~~paternity~~] **parentage**, who has attained the age of eighteen at the time of execution of the acknowledgment shall have the right to rescind the acknowledgment within the earlier of sixty days from the date of signing the acknowledgment or the date of an administrative or a judicial proceeding (including, but not limited to, a proceeding to establish a support order) relating to the child in which either signatory is a party; provided that for purposes of this section, the "date of an administrative or a judicial proceeding" shall be the date by which the respondent is required to answer the petition.

(d) A signatory to an acknowledgment of [~~paternity~~] **parentage**, who has not attained the age of eighteen at the time of execution of the acknowledgment, shall have the right to rescind the acknowledgment anytime up to sixty days after the signatory's attaining the age of eighteen years or sixty days after the date on which the respondent is required to answer a petition (including, but not limited to, a petition

to establish a support order) relating to the child in which the signatory is a party, whichever is earlier; provided, however, that the signatory must have been advised at such proceeding of his or her right to file a petition to vacate the acknowledgment within sixty days of the date of such proceeding.

(e) After the expiration of the time limits set forth in paragraphs (c) and (d) of this subdivision, any of the signatories may challenge the acknowledgment of [~~**paternity**~~] **parentage** in court only on the basis of fraud, duress, or material mistake of fact, with the burden of proof on the party challenging the voluntary acknowledgment. The acknowledgment shall have full force and effect once so signed. The original or a copy of the acknowledgment shall be filed with the registrar of the district in which the birth certificate has been filed.

3. (a) An **executed** acknowledgment of [~~**paternity**~~] **parentage** executed by [~~**the mother and father of a child born out of wedlock**~~] **any two people eligible to sign such an acknowledgment under paragraph (b) of subdivision one of this section, married or unmarried,** shall establish the [~~**paternity**~~] **parentage** of a child and shall have the same force and effect as an order of [~~**paternity**~~] **parentage** or filiation issued by a court of competent jurisdiction. Such acknowledgement shall thereafter be filed with the registrar pursuant to subdivision one or two of this section.

(b) A registrar with whom an acknowledgment of [~~**paternity**~~] **parentage** has been filed pursuant to subdivision one or two of this section shall file the acknowledgment with the state department of health and the putative father registry.

4. **The court shall give full faith and credit to an acknowledgment of parentage effective in another state if the acknowledgment was in a signed record and otherwise complies with the law of the other state.**

5. A new certificate of birth shall be issued if the certificate of birth of [~~**a**~~] **the** child [~~**born out of wedlock**~~] as defined in paragraph (b) of subdivision one of section four thousand one hundred thirty-five of this article has been filed without entry of the name of the [~~**father**~~] **signatory other than the person who gave birth**, and the commissioner thereafter receives a notarized acknowledgment of [~~**paternity**~~] **parentage** accompanied by the written consent of the [~~**putative father and mother**~~] **person who gave birth to the child and other signatory** to the entry of the name of such [~~**father**~~] **person**, which consent may also be to a change in the surname of the child.

6. Any reference to an acknowledgment of paternity in any law of this state shall be interpreted to mean an acknowledgment of parentage signed pursuant to this section or signed in another state consistent with the law of that state.

§ 8. The article heading of article 8 of the domestic relations law, as added by chapter 308 of the laws of 1992, is amended to read as follows:

GENETIC SURROGATE PARENTING CONTRACTS

§ 9. The general business law is amended by adding a new article 44 to read as follows:

ARTICLE 44

REGULATION OF SURROGACY PROGRAMS

1403. Regulations.

§ 1400. Definitions. As used in this section:

(a) The definitions in section 581-102 of the family court act shall apply.

(b) "Payment" means any type of monetary compensation or other valuable consideration including but not limited to a rebate, refund, commission, unearned discount, or profit by means of credit or other valuable consideration.

(c) "Surrogacy program" does not include any party to a surrogacy agreement or any person licensed to practice law and representing a party to the surrogacy agreement, but 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.

§ 1401. Programs regulated under this article. The provisions of this article apply to surrogacy programs arranging or facilitating transactions contemplated by a surrogacy agreement under part four of article five-C of the family court act if:

(a) The surrogacy program does business in New York state;

(b) A person acting as surrogate who is party to a surrogacy agreement resides in New York state during the term of the surrogacy agreement; or

(c) Any medical procedures under the surrogacy agreement are performed in New York state.

§ 1402. Conflicts of interest; prohibition on payments; funds in escrow; licensure; notice of surrogates' bill of rights. A surrogacy program to which this article applies:

(a) Must keep all funds paid by or on behalf of the intended parent or parents in a separate, licensed escrow fund;

(b) May not be owned or managed, in any part, directly or indirectly, by any attorney representing a party to the surrogacy agreement;

(c) May not pay or receive payment, directly or indirectly, to or from any person licensed to practice law and representing a party to the surrogacy agreement in connection with the referral of any person or party for the purpose of a surrogacy agreement;

(d) May not pay or receive payment, directly or indirectly, to or from any health care provider providing any health services, including assisted reproduction, to a party to the surrogacy agreement; and

(e) May not be owned or managed, in any part, directly or indirectly, by any health care provider providing any health services, including assisted reproduction, to a party to the surrogacy agreement.

(f) Must be licensed to operate in New York state pursuant to regulations promulgated by the department of financial services in consultation with the department of health.

(g) Must ensure that all potential parties to a surrogacy agreement, at the time of consultation with such surrogacy program, are provided with written notice of the surrogates' bill of rights enumerated in part six of article five-C of the family court act.

§ 1403. Regulations. The department of financial services, in consultation with the department of health, shall promulgate regulations to implement the requirements of this article, and shall annually report to the state legislature regarding the practices of surrogacy programs and all business transactions related to surrogacy in New York state, with recommendations for any necessary amendments to this article.

§ 10. The public health law is amended by adding a new article 25-B to read as follows:

ARTICLE 25-B

GESTATIONAL SURROGACY

Section 2599-cc. Gestational surrogacy.

§ 2599-cc. Gestational surrogacy. 1. The commissioner shall promulgate regulations on the practice of gestational surrogacy. Such regulations shall include, but not be limited to:

(a) guidelines and procedures for obtaining fully informed consent from potential persons acting as surrogates, including but not limited to a full disclosure of any known health risks associated with acting as a surrogate;

(b) the development and distribution, in printed form and on the department's website, of informational material relating to gestational surrogacy; and

(c) the establishment of a voluntary central tracking registry of persons acting as surrogates, as reported by surrogacy programs licensed by the department pursuant to article forty-four of the general business law upon the affirmative consent of a person acting as surrogate. Such registry shall provide a means for gathering and maintaining accurate information on the:

(i) number of times a person has acted as a surrogate;

(ii) health information of the person acting as surrogate; and

(iii) other information deemed appropriate by the commissioner.

2. All such regulations shall maintain the anonymity of the person acting as surrogate and any resulting offspring and govern access to information maintained by the registry.

§ 11. Subdivisions 4, 5, 6, 7 and 8 of section 4365 of the public health law are renumbered subdivisions 5, 6, 7, 8, and 9 and a new subdivision 4 is added to read as follows:

4. The commissioner, in consultation with the transplant council, shall promulgate regulations on the donation of ova. Such regulations shall include, but not be limited to:

(a) guidelines and procedures for obtaining fully informed consent from potential donors, including but not limited to a full disclosure of any known health risks of the ova donation process;

(b) the development and distribution, in printed form and on the department's website, of informational material relating to the donation of ova; and

(c) the establishment of a voluntary central tracking registry of ova donor information, as reported by banks and storage facilities licensed pursuant to this article upon the affirmative consent of an ova donor. Such registry shall provide a means for gathering and maintaining accurate information on the:

(i) number of ova donated from a single donor;

(ii) health information of the donor at the time of the donation; and

(iii) other information deemed appropriate by the commissioner.

In addition, all such regulations shall maintain the anonymity of the donor and any resulting offspring and govern access to information maintained by the registry.

§ 12. This act shall take effect on the one hundred twentieth day after it shall have become a law. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such date.

A01071 Chamber Video/Transcript:

The Child-Parent Security Act

February 11, 2020

Today's Agenda

- Overview of the Child-Parent Security Act
- Local Registrar Responsibilities
- DOH and OTDA Contacts
- Q & A

The Child-Parent Security Act

- The Child-Parent Security Act (CPSA) is a law in New York State that legalizes gestational surrogacy and provides a simple path to establish legal parental rights for parents who rely on assisted reproductive technology (ART) to have children.
- Introduces the new documentation to amend the birth certificate:
  - Acknowledgement of Parentage (AoP)
  - Surrogacy Agreement
  - Order of Parentage
- **Effective: February 15, 2021**

The Child-Parent Security Act (cont.)

- Establishes legal criteria for gestational surrogacy agreements that provide the strongest protections in the nation for parents and surrogates, ensuring all parties provide informed consent at every step of the process;
- Creates a Surrogates' Bill of Rights, to ensure the unfettered right of surrogates to make their own healthcare decisions, including whether to terminate or continue a pregnancy, and that surrogates have access to comprehensive health insurance and independent legal counsel of their choosing, all paid for by the intended parents; and
- Creates a streamlined process for establishing parenthood when one of the individuals is a non-biological parent

Benefits of establishing parentage:

- Legal record of the identity of both parents
- Both parents' names will appear on the birth certificate
- Better access to information on family medical history
- Emotional benefit of knowing both parents
- Financial support, health or life insurance
- Right to inherit from the other parent
- Share child-related responsibilities
- Parental rights legally established

The Acknowledgement of Parentage (AOP)

- Formerly known as the Acknowledgement of Paternity – this document continues to be a voluntary document to add parental rights to the non-birthing parent.
- Filing procedure remains ***unchanged***
- **Reminder:** Search for the initial birth record before accepting the AoP – carefully review what you have on file
  - If there is an amended birth record on file – REJECT the AOP
  - If a secondary parent exists on the original birth certificate - REJECT THE AOP
- Rejected AoPs are not sent to the Putative Father Registry or the State Health Department

The Acknowledgement of Parentage (AOP)

- **An Acknowledgment of Parentage is void at the time of signing if:**

1. A person other than the parties signing the Acknowledgment of Parentage is a presumed parent of the child due to marriage under New York Domestic Relations law;
2. The child has a legally recognized parent other than the parties signing the Acknowledgment of Parentage due to an assisted reproduction agreement;
3. A court has already entered a judgment or order determining parentage for the child;
4. Another person has voluntarily acknowledged parentage for the child;
5. A person signing the Acknowledgment of Parentage was a donor in an assisted reproduction, and already signed a statement that the donation was not intended to result in parental rights and responsibilities; or
6. A person signing the Acknowledgment of Parentage asserts that they have parental rights due to an assisted reproduction agreement, but a court finds that the child was not conceived through assisted reproduction.

Surrogacy Agreement

- A contractual agreement where intended parents utilize a surrogate to have a child.
  - The surrogate is never intended to be the parent of the child.
  - The surrogacy agreement outlines who will be the legal parent of the child to be placed on the birth certificate.*
- File the original birth record – BUT DO NOT issue the original birth record (original record should be sealed)
  - ***Note: Please continue to send the original birth certificate to DOH***
- The State Health Department will issue an amended birth record to the Local Registrar
- The Local Registrar should have a copy of the surrogacy agreement
  - The surrogacy agreement should be provided from the hospital, family, or DOH

* (Just be aware of these circumstances in the surrogacy agreement)

Order of Parentage

- The Order of Parentage is an order issued by a court of competent jurisdiction which legally establishes the parents to a child
  - This may occur at the time of birth or any time thereafter.
- File the original birth record, but DO NOT ISSUE the original birth record if both parents or the birth parent are being altered
  - ***Note: Please continue to send the original birth certificate to DOH***
- The State Health Department will issue an amended birth record if both parents or the birth parent are being changed
- Be vigilant on what is being amended by the order of parentage

Local Registrar Roles & Responsibilities

- If you are made aware that a birth certificate is affected by an AoP, Surrogacy Agreement or Order of Parentage, make sure you get a copy.
- Search your records to ensure that there is no current birth certificate on file.
- If the AoP, Surrogacy Agreement or Order of Parentage effects an existing parent on an existing birth certificate, DO NOT Amend the document.
  - If it is an AoP, please REJECT the AoP. Do not send the AoP to the State Health Department or the Putative Father Registry.
    - Please inform the applicant that a court order will be needed to make the changes to the birth certificate.
    - If the applicant continues to question, please send them to the State Health Department
  - If it is a Surrogacy Agreement or Order of Parentage – send them to the State Health Department for an amendment
    - Please seal the record.
- Any questions – please contact the State Health Department.

New York State Contacts

- Questions about the birth certificate as it relates to the AoP, Surrogacy Agreements and/or Orders of Parentage
  - The Dept. of Health/Bureau of Vital Records:
    - vr@health.ny.gov
- Questions about the AoP or the Putative Father Registry only:
  - The Office of Temporary Disability Assistance:
    - otda.sm.dcse.parentage@otda.ny.gov

Question & Answer

Please type your questions into the chat.


Thank you

Gestational Surrogacy Fact Sheet

This fact sheet provides basic information about gestational surrogacy. Gestational surrogacy is a type of surrogacy where the surrogate does not provide the egg for fertilization.

There is another type of surrogacy called "genetic surrogacy." This fact sheet does not cover genetic surrogacy. Recent changes to laws in New York do not cover genetic surrogacy. For questions about genetic surrogacy, talk with your health care provider or infertility specialist.

If you are interested in learning more about gestational surrogacy, visit the resources at the end of this sheet, or talk with a health care professional or an attorney who specializes in surrogacy.

What is gestational surrogacy?

Gestational surrogacy is a process where one person, who did not provide the egg used in conception, carries a fetus through pregnancy and gives birth to a baby for another person or couple. The person who carries the fetus is called a "surrogate" or "gestational carrier." The person or couple who are seeking to parent the baby or babies are called the "intended parent(s)."

Who chooses surrogacy to become a parent?

Many people choose surrogacy as a way to start or add to their family. Most commonly, intended parents are:

- Not able to have children because of infertility;
- Not able to safely give birth to a child because of health conditions;
- Same-sex male couples;
- Transgender individuals or couples; or
- Prospective single males.

Who can be a surrogate?

Surrogates should have had healthy pregnancies in the past and a desire to help intended parents who are unable to have children. A surrogate may carry a fetus for someone they don't know, or for a friend or relative.

What does it take to be a surrogate or an intended parent?

Surrogates must be screened to make sure they are healthy enough to have a baby. Medical guidelines, including Department of Health surrogacy screening guidelines, recommend that surrogates be between 21 and 45 years of age, have had at least one healthy pregnancy and a full-term delivery without complications. Medical screening includes:

- blood tests and other lab work;
- a physical exam;
- a psychosocial exam; and
- consultation with the health care provider.

Other screenings may be ordered by health care providers who are experts in surrogacy and reproductive health. These screenings help to make sure that the surrogate is medically appropriate to serve as a surrogate and fully understands any potential risks.

Intended parents are screened to make sure they are ready to begin the surrogacy process. This includes being physically, mentally and legally capable of parenting and can afford potential costs associated with the surrogacy process.

If an intended parent is providing the egg or sperm, they may be screened for various health issues, as well as genetic conditions. Genetic screening is not done to reveal physical characteristics not harmful to a baby, like hair color, eye color or sex.

New York State law requires certain New York State residency requirements for the intended parent(s) and surrogate (*see*Family Court Act § 581-402[a],[b]).

Who else is involved in the gestational surrogacy process?

- **Attorneys:** The surrogate and the intended parent(s) must be represented by separate legal counsel who are licensed in New York State and have expertise in surrogacy matters. The attorneys draft and review legal documents to make sure their client(s)' (the surrogate or intended parent(s)) interests are protected. They also help their client(s) understand their rights and responsibilities included in the surrogacy agreement.
- **Surrogacy matching programs:** Some intended parents may go through a surrogacy matching program, also called a *surrogacy agency*. These programs:
    - coordinate the many services that are part of the surrogacy process;
    - work to make sure that everyone's interests are protected;
    - can refer the surrogate and intended parent(s) to attorneys who can help them with the legal aspects of surrogacy;
    - can refer the intended parents and surrogates to qualified health care providers.

In New York State, surrogacy programs must be licensed by the New York State Department of Health and follow the Department's guidelines.

- **Egg and sperm donors:**Some intended parents choose to use sperm or egg(s) from a sperm or egg bank. There are many reasons why they may choose to use donated sperm or eggs. In New York State, gestational surrogates cannot donate their own eggs as part of a surrogacy agreement.
- **Health care providers**: Some health care providers specialize in surrogacy arrangements. These providers include:
    - An *obstetrician* or *obstetrician/gynecologist* (an OB/GYN): a doctor with training in pregnancy and reproduction. They provide the primary medical care for the surrogate during the pregnancy. Other health care providers, including nurse midwives, nurses and doulas may also be involved in the surrogate's care.

  - A *reproductive endocrinologist*: an obstetrician who also has special training in diagnosing and treating infertility. They use medical procedures like in vitro fertilization, or IVF, to help surrogates become pregnant.
  - A *fertility clinic* or *IVF clinic*: A group of providers who provide medical screening and services required by those who need medical help to achieve a pregnancy.
- **Mental health professionals:** Mental health professionals meet with the surrogate and their partner (if any) to make sure that they are emotionally prepared for the surrogacy process. This includes assessing that they have thought through the potential emotional risks and the impact of the process on their families. Intended parents also meet with mental health professionals, to make sure that they understand the surrogacy process and are able to care for the child.

If I am using surrogacy, will others know about my health information?

Privacy and confidentiality are very important. All professionals that work with surrogates and intended parents must keep their client(s)' medical information private and confidential. They also cannot share information about the child being born through surrogacy.

A surrogate may be asked to share information about their medical history and the health of the pregnancy with the intended parent(s).

Surrogates and intended parents often meet in person before the pregnancy. They usually keep in contact during the pregnancy. The intended parent(s) are usually at the hospital during the child's birth.

How does surrogacy work?

The first step in surrogacy is for the intended parent(s) to select a surrogate. The surrogate and intended parent(s) are screened to make sure they are healthy (both physically and emotionally) and are able to participate in the surrogacy process. Once a surrogate is matched with the intended parent(s), the parties work with their separate attorneys to write, review, revise and sign the surrogacy agreement. This happens before the start of any medical procedures (other than screening tests.)

The surrogacy agreement describes the rights and responsibilities of the surrogate and the intended parent(s) and the promises (agreement) the parties are making to one another. New York State law is very specific about the requirements of the agreement (*see*Family Court Act § 581-403). Surrogacy matching programs and attorney for the surrogate and intended parent(s) must ensure that all requirements are met under New York State law to ensure the agreement is legally binding and enforceable, and to best protect the interests and rights of all parties to the agreement.

After the surrogacy agreement is signed, an embryo can be transferred into the surrogate through IVF. IVF is a medical procedure where an egg is fertilized with sperm in a laboratory. This creates an embryo that is transferred into the surrogate's uterus. The surrogate usually takes medication before the embryo is transferred. This makes the IVF procedure more likely to result in a pregnancy.

What is included in a surrogacy agreement and required under New

York law?

Surrogates have a right to the following, to be provided and paid for by the intended parent(s):

- the right to comprehensive health insurance coverage. This insurance must cover the surrogate through the entire surrogacy process, from the time the surrogate takes any medications before or after the embryo transfer, throughout the pregnancy, and for 12 months after the pregnancy ends (whether resulting in the child's birth, stillbirth, or termination of the pregnancy);
- a disability insurance policy;
- a life insurance policy;
- a comprehensive health insurance policy that covers mental health counseling; and
- compensation for legal fees.

Surrogates also have the following rights under New York law:

- the right to select a health care professional of their own choosing;
- the right to terminate or continue the pregnancy;
- the right to make health and welfare decisions about themselves and the pregnancy, including the right to reduce or retain the number of fetuses or embryos they are carrying;
- the right to receive compensation for the surrogacy, which must be held in escrow with an independent escrow agent; and
- the right to be provided with a copy of the Surrogate's Bill of Rights.

The surrogacy agreement is a long document, and includes additional information related to the surrogacy process.

Surrogacy matching programs and attorneys for the surrogate and intended parent(s) must refer to the full legal requirements set forth in New York law, including but not limited to the requirements for a surrogacy agreement, set forth in Family Court Act Article 5-C, Part 4, and the Surrogate's Bill of Rights, set forth in Family Court Act Article 5-C, Part 6. The above lists are not intended to be exhaustive or serve as legal guidance.

How much does surrogacy cost?

Surrogacy can be costly, and the price range varies. Costs can include legal fees, medical expenses, surrogacy agency fees, the surrogate's compensation, and other miscellaneous expenses. Many surrogacy arrangements cost between $60,000 and $150,000.

Are there risks with being a surrogate?

Yes, anyone considering surrogacy must be aware of the potential risks associated with being a surrogate. There are health risks to the surrogate as with any pregnancy. Most pregnant people have mild or moderate symptoms like nausea and vomiting, minor swelling, and fatigue. In rare cases, pregnant people experience more serious medical complications, including death, even if they were healthy before becoming pregnant. These risks will be discussed as part of the surrogacy process, and surrogates must be screened for possible

health risks.

Getting routine health care during and after a pregnancy is an important part of the surrogacy process. This may help identify any health problems before they become severe.

For more information on the health risks associated with pregnancy, talk with your health care provider or visit Pregnant or Just Had a Baby? Know When to Call for Help - Fast!.

Being a surrogate can be time-consuming and emotional. If the surrogate is married, that person generally must also be involved and willingly cooperate in the surrogacy arrangement. Although not genetically related, the surrogate may become attached to the baby they are carrying. While most surrogates experience joy and pride because of the vital role they play in assisting the intended parent(s) to have a child, some surrogates may find the process emotionally challenging.

Are there risks to Intended Parent(s) using a surrogate?

There may be emotional and financial risks for the intended parent(s). For example, the intended parent(s) can become emotionally attached to a surrogate but frustrated by their lack of control over the surrogate's lifestyle and pregnancy. Also, there is no guarantee that the surrogate will become pregnant after the embryo is transferred in their uterus, and each cycle of IVF can be costly. There may be complications during the pregnancy which may put the surrogate's health, or the health of the fetus, at risk. Finally, there is no guarantee that the pregnancy will go to term and or that the child will be born healthy.

Where can I find out more about infertility and surrogacy?

- American Society for Reproductive Medicine
- The National Infertility Association

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 filing with the Secretary of State:

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] Family Health

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 to 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.

(c) 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.

(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 filing with the Department of State. 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.

EMERGENCY JUSTIFICATION

There have been documented cases in which the owners of business 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. When Laws of 2020, Chapter 56, Part L, goes into effect on February 15, people in New York may begin to enter into surrogacy agreements even if the Department does not promulgate these regulations. There is a danger that the parties involved will not follow guidelines and best practices relating to screening of surrogates and intended parents. There is also a danger that guidelines and best practices relating to screening of ova donors will not be followed.

If these regulations are not in place when gestational surrogacy becomes legal in New York, there is a danger that medical procedures will take place without the necessary investigation and evaluation to promote a safe outcome for both the surrogate and the child who is born. The surrogate must be given proper medical examination to assess the surrogate's physical and mental health in order to make sure the surrogate is suitable. A psychological assessment increases the likelihood that the surrogate has the ability keep both the surrogate and the developing child healthy through the pregnancy, labor and delivery. The surrogate's physical and mental health during gestation could affect the child's health and wellbeing. The age and reproductive history of the surrogate should be evaluated prior to undertaking gestational surrogacy.

Surrogacy arrangements must not take advantage of people who may want to become surrogates, and in the absence of these regulations, there is a danger that gestational surrogates may not have all of the supportive services needed during and after the birth. Gestational surrogates must have certainty that they will be fairly compensated and that the intended parents will accept custody of the children regardless of the number, gender, or mental or physical

condition. There is also a need to protect intended parents from entering into binding contracts that could compromise the child's health or not result in the person acting as surrogate voluntarily surrendering custody to the intended parents upon the birth of the child. These regulations will ensure that surrogacy arrangements comply with legal and ethical rules for gestational surrogacy.

In the absence of these regulations, the health and safety of gestational surrogates and babies born under surrogacy agreements would be in serious jeopardy, and the State of New York would have little leverage to take action against those responsible for the execution of unethical surrogacy arrangements that result in bad health outcomes.

The Child-Parent Security Act: Gestational Surrogacy Agreements, Acknowledgment of Parentage and Orders of Parentage

Overview

Vital Records may amend the names of the intended parents on birth records for all of New York State except New York City. It does not have these records for New York City (the boroughs of Manhattan, Kings (Brooklyn), Queens, Bronx, and Richmond (Staten Island)).

The Child-Parent Security Act

The Child-Parent Security Act (CPSA) is a law in New York State that legalizes gestational surrogacy and provides a simple path to establish legal parental rights for parents who rely on assisted reproductive technology (ART) to have children. The CPSA goes into effect on February 15, 2021.

The CPSA:

- Establishes legal criteria for gestational surrogacy agreements that provide the strongest protections in the nation for parents and surrogates, ensuring all parties provide informed consent at every step of the process;
- Creates a Surrogates' Bill of Rights, to ensure the unfettered right of surrogates to make their own healthcare decisions, including whether to terminate or continue a pregnancy, and that surrogates have access to comprehensive health insurance and independent legal counsel of their choosing, all paid for by the intended parents; and
- Creates a streamlined process for establishing parenthood when one of the individuals is a non-biological parent

The Act introduces new documentation to amend the birth certificate:

- Acknowledgement of Parentage (AoP)
- Gestational Surrogacy Agreement
- Order of Parentage

Acknowledgment of Parentage (AoP)

The following persons may sign an AoP:

- An unmarried person who gave birth to the child and another person who is a genetic parent;
- A married or unmarried person who gave birth to the child and another person who is an intended parent of the child, in accordance with the Family Court Act Section 581-303, conceived through

assisted reproductive technologies

The AoP is void if the following occur:

- A person other than the parties signing the Acknowledgment of Parentage is a presumed parent of the child due to marriage under New York Domestic Relations law;
- The child has a legally recognized parent other than the parties signing the Acknowledgment of Parentage due to an assisted reproduction agreement (an agreement with a gamete donor);
- A court has already entered a judgment or order determining parentage for the child;
- Another person has voluntarily acknowledged parentage for the child;
- A person signing the Acknowledgment of Parentage was a donor in an assisted reproduction, and already signed a statement that the donation was not intended to result in parental rights and responsibilities; or
- A person signing the Acknowledgment of Parentage asserts that they have parental rights due to an assisted reproduction agreement, but a court finds that the child was not conceived through assisted reproduction.

Filing:

An AoP must be submitted to either:

- the birth registrar (or representative) in the hospital where the child is born at the time of birth; or
- the local registrar in the registration district where the child was born.
- The local registrar will forward the documentation to the State Health Department where the birth certificate will be amended to reflect the information in a valid AoP.

LDSS Acknowledgment of Parentage (PDF)
Use this form for adding the non-birth parent's name under the above-mentioned circumstances

Gestational Surrogacy Agreements

The first step in surrogacy is for the intended parent(s) to select a surrogate. The surrogate and intended parent(s) are screened to make sure they are healthy (both physically and emotionally) and able to participate in the surrogacy process. Once a surrogate is matched with the intended parent(s), the parties work with their separate attorneys to write, review, revise and sign the surrogacy agreement. This happens before the start of any medical procedures (other than screening tests.)

The surrogacy agreement describes the rights and responsibilities of the surrogate and the intended parent(s) and the promises (agreement) the parties are making to one another. New York State law is very specific about the requirements of the agreement (*see*Family Court Act § 581-403). Surrogacy matching programs and attorneys for the surrogate and intended parent(s) must ensure that all requirements are met under New York State law to ensure the agreement is legally binding and enforceable, and to best protect the interests and rights of all parties to the agreement.

After the surrogacy agreement is signed, an embryo can be transferred into the surrogate through IVF. IVF is a medical procedure where an egg is fertilized with sperm in a laboratory. This creates an embryo that is

transferred into the surrogate's uterus. The surrogate usually takes medication before the embryo is transferred. This makes the IVF procedure more likely to result in a pregnancy.

In New York State, the gestational surrogates **have a right to the following, to be provided and paid for by the intended parent(s):**

- the right to comprehensive health insurance coverage.[1] This insurance must cover the surrogate through the entire surrogacy process, from the time the surrogate takes any medications before or after the embryo transfer, throughout the pregnancy, and for 12 months after the pregnancy ends (whether resulting in the child's birth, stillbirth, or termination of the pregnancy);
- a disability insurance policy;
- a life insurance policy;
- a comprehensive health insurance policy that covers mental health counseling; and
- compensation for legal fees.

Surrogates also have the following rights under New York law:

- the right to select a health care professional of their own choosing;
- the right to terminate or continue the pregnancy;
- the right to make health and welfare decisions about themselves and the pregnancy, including the right to reduce or retain the number of fetuses or embryos they are carrying;
- the right to receive compensation for the surrogacy, which must be held in escrow with an independent escrow agent; and
- the right to be provided with a copy of the Surrogate's Bill of Rights.

The gestational surrogacy agreement is a long document, and includes additional information related to the surrogacy process.

Surrogacy matching programs and attorneys for the surrogate and intended parent(s) must refer to the full legal requirements set forth in New York law, including but not limited to the requirements for a gestational surrogacy agreement, set forth in Family Court Act Article 5-C, Part 4, and the Surrogate's Bill of Rights, set forth in Family Court Act Article 5-C, Part 6. The above lists are not intended to be exhaustive or serve as legal guidance.

Gestational surrogacy can be costly, and the price range varies. Costs can include legal fees, medical expenses, surrogacy agency fees, surrogate's compensation (payments to a person acting as surrogate are limited to the duration of the pregnancy and a recuperative period of up to eight weeks after the birth of any child), and other miscellaneous expenses. Many surrogacy arrangements cost between $60,000 and $150,000.

Filing:

- A gestational surrogacy agreement must be submitted to the birth registrar in the hospital where the child is born prior to or at the time of birth;
- The local registrar will forward the documentation to the State Health Department where the birth certificate will be amended to reflect the information in a gestational surrogacy agreement.

Orders of Parentage

A petition for judgment of parentage or non-parentage of a child conceived through assisted reproduction may be initiated in Family Court by:

- A child;
- A parent;
- A participant;
- A person with a claim to parentage;
- A social service official or other governmental agency authorized by other law; or
- A legal representative for the individual who would have otherwise been entitled to bring a petition to establish parentage from a child born through assisted reproduction or pursuant to a gestational surrogacy agreement - but who is deceased, incapacitated, or a minor.

Court Clerk:

Shall submit a notification of an order of parentage to the State Health Department

Filing:

In addition to the notice from the Court Clerk, an Order of Parentage must be submitted:

- To the birth registrar in the hospital where the child is born at or prior to or at the time of birth; or
- To the local registrar in the registration district where the child is born; or
- The local registrar will forward the documentation to the State Health Department where the birth certificate will be amended to reflect the information in the Order of Parentage.

Original Birth Certificate is sealed

The original birth certificate and all other documents relating to the changes will be retained in a sealed file. Only the amended birth certificate will be released upon future requests for a certified birth certificate.

Local Registrars

Training Program

Pre-recorded training is available for the Child-Parentage Security Act / Acknowledgment of Parentage-20210211 1505-1.

Please Note: The Webex Player must be installed on your computer for you to attend any of the webinar presentations - recorded or live. Please see Instructions to Access Webex Webinar Training (PDF).

Documentation and Publications

Click the links below to open these PDF documents. You will need Adobe Acrobat Reader installed on your computer to view PDF documents.Download the free Adobe Reader.

- Power Point presentation for the Child Parent Security Act Training Session for Local Registrars (PDF)
- Consolidated Question and Answers from the Training Session (PDF)

Fees

The first copy of the amended new birth certificate is free to the birth parent.

For more information on the Gestational Surrogacy, Surrogacy Screening Guidelines, Surrogates' Bill of Rights and Ova and Oocyte donation

For more information on Gestational Surrogacy, Surrogacy Screening Guidelines, Surrogates' Bill of Rights and Ova and Oocyte donation please see The Child-Parent Security Act: Gestational Surrogacy.

Notes

1. A surrogate who does not receive any compensation for the surrogacy may waive the right to have the intended parent(s) pay for the health insurance policy and associated costs (e.g., co-pays). *See*Family Court Act § 581-402[7]); *but see* Family Court Act § 581-403(g).