REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGIES

Issue Description

Infertility affects approximately 12 percent of the reproductive-age population in the United States. The advancement of scientific technology over the years has provided infertile couples with a variety of options for having a child, including in vitro fertilization, artificial insemination, and third-party reproduction, such as sperm or egg donation and surrogacy. Collectively these technologies are referred to as assisted reproductive technologies (ART).

There are social, scientific, and commercial components associated with ART, and, as a result, there are a wide variety of players involved in the use of ART. These individuals and organizations include: psychiatrists, psychologists, or counselors; medical doctors, technicians, and health care administrators; clinics, hospitals, and related facilities; egg and sperm donors and surrogates; intended parents; and attorneys. In addition, third-party reproduction techniques have created a market for agencies that, on a commercial basis, recruit egg and sperm donors and surrogates and connect them with intended parents, as well as facilitate the various medical and legal procedures related to third-party reproduction. In light of its many components and players, ART may raise a variety of public policy considerations. The significant financial investment required of intended parents, in particular, may raise consumer-protection considerations related to the commercial components of ART. For example, in early 2009 a class-action lawsuit was filed against SurroGenesis, a California-based surrogacy agency, alleging that between $2.5 and $5 million had disappeared from the business’ accounts due to misappropriation by the owner.

Although there are some federal laws that indirectly affect ART, there is only one federal statute that directly regulates this area. Primarily, ART is regulated among the states through legislative action or state court decisions. In Florida, egg, sperm, and preembryo donation and gestational surrogacy are regulated by ch. 742, F.S., relating to determination of parentage. Specifically, Florida law governs the status of a child conceived by a form of assisted reproductive technology; the donation of eggs, sperm, or preembryos; the requirements of a gestational surrogacy contract; and the disposition of eggs, sperm, or preembryos. Florida does not currently regulate the agencies that provide third-party reproductive services.

The purpose of this interim report is to review current practices, as well as case law, statutes, and legal scholarship, associated with assisted reproductive technology in Florida and other jurisdictions to evaluate potential changes to Florida law regarding assisted reproductive technologies in order to help avoid potential abuse related to the commercial components of these practices and to identify other potential regulations Florida may wish to adopt.

Background

An estimated 7.3 million couples in the United States – about 12 percent of the reproductive-age population – experience infertility. The advancement of scientific technology over the years has provided infertile couples with a variety of options for having a child. Artificial insemination appears to be the oldest and most widely used

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method of assisted reproductive technology (ART). However, in vitro fertilization, embryo transfer, and surrogacy have also gained popularity.

There are two types of surrogacy: traditional surrogacy and gestational surrogacy. Traditional surrogacy has been defined as “an 'agreement wherein a woman agrees to be artificially inseminated with the semen of another woman’s husband; she is to conceive a child, carry the child to term and after the birth, assign her parental rights to the birth father and his wife.’” In traditional surrogacy, the surrogate mother is genetically related to the child. The second type of surrogacy is gestational surrogacy, which uses in vitro fertilization to create an embryo that is then transferred into the uterus of the surrogate. In gestational surrogacy, the embryo is created by using “the intended mother’s egg and intended father’s sperm, or some other combination using donor egg and sperm.” The first case of gestational surrogacy in the United States was reported in 1985, and the technique has become increasingly popular, now accounting for approximately 95 percent of all surrogate pregnancies in the United States.

Although there are some federal laws that indirectly affect different areas of ART, the Fertility Clinic Success Rate and Certification Act of 1992 is the only federal statute that is directly aimed at regulating it. The United States Supreme Court has not yet regulated or addressed the issue. Primarily, ART is regulated among the states through legislative action or state court decisions. For example, as of 1999, almost half of the states had enacted legislation addressing surrogacy in varying degrees.

In Florida, egg, sperm, and preembryo donation and gestational surrogacy are regulated by ch. 742, F.S., relating to determination of parenthood. Section 742.14, F.S., provides that the donor of any egg, sperm, or preembryo, with certain exceptions, shall relinquish all maternal or paternal rights and obligations relating to the donation or any resulting children. The statute provides that only reasonable compensation directly related to the donation of eggs, sperm, and preembryos is permitted.

Section 742.15, F.S., governs gestational surrogacy contracts and provides that the gestational surrogate must be 18 years of age or older, and the commissioning couple must be legally married and both be at least 18 years old. A couple may only enter into a gestational surrogacy contract if the commissioning mother cannot physically gestate a pregnancy to term, the gestation will cause a risk to the physical health of the commissioning mother, or the gestation will cause a risk of health to the fetus. A gestational surrogacy contract must include the following provisions:

- The commissioning couple agrees that the gestational surrogate shall be the sole source of consent with respect to clinical intervention and management of the pregnancy;
- The gestational surrogate agrees to submit to reasonable medical evaluation and treatment and to adhere to reasonable medical instructions about her prenatal health;

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5 In vitro fertilization is a process in which doctors remove eggs from a woman, which are then placed in a petri dish where fertilization occurs with the sperm of the male donor. Smith, supra note 2.
8 For further discussion of the Fertility Clinic Success Rate and Certification Act, see the Findings and Conclusions section of this report.
9 Behm, supra note 3, at 582.
The gestational surrogate agrees to relinquish any parental rights upon the child’s birth and to proceed with statutory judicial proceedings;

- The commissioning couple agrees to accept custody of and to assume full parental rights and responsibilities for the child immediately upon the child’s birth, regardless of any impairment of the child; and

- The gestational surrogate agrees to assume parental rights and responsibilities for the child born to her if it is determined that neither member of the commissioning couple is the genetic parent of the child.

The commissioning couple may pay reasonable living, legal, medical, psychological, and psychiatric expenses of the gestational surrogate that are directly related to prenatal, intrapartal, and postpartal periods.

After the birth of the child, the commissioning couple must petition the court for a hearing in order to receive an expedited affirmation of parental status. The court shall issue an order stating that the commissioning couple are the legal parents of the child if the court determines that a binding and enforceable gestational surrogacy contract has been executed and that at least one member of the commissioning couple is the genetic parent of the child. 10

The only persons who may rely on the current statute to receive an expedited affirmation of parental status are a commissioning couple. The statute, as promulgated in 1993, does not appear to contemplate single parents taking advantage of gestational surrogacy. If a single person uses the services of a surrogate to carry his or her embryo, that person must go through an adoption process in order to have his or her name placed on the birth certificate as the natural parent, even if the person is genetically related to the child.

The activity of assisted reproductive technology involves a social component, a science component, and a commercial component. Often the stories that make the news involve the social and scientific components of ART. For example, there was much criticism in January 2009 when Nadya Suleman gave birth to octuplets, earning her the nickname of “Octomom” and generating debate over how many embryos a doctor should implant in a woman during in vitro fertilization. Intrauterine insemination, another form of ART that often produces multiple children, has also generated debate regarding whether doctors are prescribing excessive doses of hormone injections, which can overstimulate the ovaries and therefore produce a large number of eggs. 11 Recently another story made headlines about a woman who was implanted with the wrong embryo. 12 However, there is also a commercial side to ART. For example, agencies that provide third-party reproductive services on a commercial basis are common players in ART because, for a fee, they will match intended parents with donors or surrogates and facilitate relationships between the parties.

During the 2009 Regular Session, SB 2640 attempted to address the brokering of various forms of ART by providing that, except for an attorney, a person may not charge or accept compensation of any kind for making a referral relating to an egg, sperm, or preembryo donor or to a gestational surrogate. However, the bill died in the Committee on Rules. Although there are scientific and social aspects of this technology, this report focuses primarily on the commercial component of ART.

**Findings and/or Conclusions**

**Assisted Reproductive Technologies in Practice** 13

Persons experiencing infertility have a variety of options available to them, such as artificial insemination, in vitro fertilization, and third-party reproduction, which involves sperm and egg donation and surrogacy. Collectively these technologies are referred to as assisted reproductive technologies (ART). Because many couples choose to

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10 Section 742.16(6), F.S.
13 As part of the research for this report, Senate professional staff spoke with ART agencies in the state, practicing attorneys, and professional organizations.
have a child using third-party reproduction, a market has developed for the recruitment of egg and sperm donors or surrogates and the matching of them with intended parents. These services may be offered on a fee basis by private businesses that develop, maintain, and provide access to databases of people who wish to be a donor or surrogate. These ART agencies can also put clients in touch with doctors or clinics that can perform the necessary medical procedures, as well as make referrals to attorneys who can draft the contracts that govern the relationship between the intended parents and the donor or surrogate. Comparable third-party database and matching services may also be offered by an attorney as a component of a law practice (i.e., an attorney-run ART agency) or as a service by a clinic or facility that principally performs ART medical procedures. For purposes of this report, the term “ART agency” will be used generally to describe an organization that provides database, matching, and other third-party reproductive services on a commercial or fee basis.

Couples who choose to have a child using third-party reproductive technology often enlist the help of an ART agency. There are many different avenues a couple may take to bring them to an ART agency. For example, a couple may have spent years trying to become pregnant, and their doctor may recommend the use of an agency to assist them in the process of third-party reproduction. Often agencies receive new clients based on word of mouth from previous satisfied clients, or sometimes a couple may find a particular agency based on a simple Internet search. Most agencies have websites, and some also have blogs, Facebook accounts, and Twitter accounts.

There are multiple costs involved in third-party reproduction. For example, a couple seeking a surrogate carrier can expect to pay a fee to an ART agency for its matching and facilitation services, which is usually nonrefundable; medical expenses (e.g., endocrinologist and hospital fees); attorney’s fees; and costs or reimbursements to the surrogate. Industry standards set by the American Society for Reproductive Medicine place a $10,000 cap on egg donor compensation; however, there is not currently a similar cap on surrogate compensation or reimbursement. Surrogates can be paid, on average, $25,000 for their services.⁴ Agency fees differ depending on the type of services provided, as well as the practice model of the agency. For example, some agencies use a tiered payment method, while others require full payment up front, and the fee may be less if the agency is coordinating a donor match versus a surrogate match. Agency fees can range between $4,000 and $20,000.¹⁵ Not including the agency fee, hiring a surrogate in the United States can cost between $40,000 and $100,000, which includes the surrogate’s compensation, insemination or in vitro fertilization costs, and costs related to medical care, transportation, and legal services.¹⁶

The use of assisted reproductive technologies is growing, and because of the amount of money that an intended parent may pay as part of the process, it is an area that some maintain is “ripe for fraud” and warrants regulation.¹⁷ The issue of whether surrogacy should be regulated gained momentum in early 2009 after a class-action lawsuit was filed against SurroGenesis, a California-based surrogacy agency, alleging that the agency and its escrow company were intertwined and that they embezzled between $2.5 and $5 million from prospective parents.¹⁸ One of SurroGenesis’ intended parents had paid the company $93,000 when the company closed.¹⁹ In another illustration of a potential problem, one practitioner raised a concern about whether immigration and citizenship issues are being clearly established by ART agencies. For example, if an agency uses a surrogate whose immigration status is in question and that surrogate is deported, it may be time-consuming and expensive to try

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⁶ Galpern, supra note 14, at 11.
⁹ Bellisle, supra note 18.
and return the child to the United States. Although research for this report did not reveal data indicating such problems in Florida, the potential for consumer problems to occur in the ART process does exist.

**State Regulation**

In an attempt "to reduce the ‘commercialization’ of surrogacy arrangements, . . . Virginia and New Hampshire statutes prohibit the use of third party brokers and payment of a fee that exceeds the surrogate mother’s actual costs in carrying and delivering the child."\(^{20}\) The New Hampshire statute provides: “No person or entity shall promote or in any other way solicit or induce for a fee, commission or other valuable consideration, or with the intent or expectation of receiving the same, any party or parties to enter into a surrogacy arrangement.”\(^{21}\) Virginia has a similar, but more expansive, provision. The Virginia Code provides:

A. It shall be unlawful for any person, firm, corporation, partnership, or other entity to accept compensation for recruiting or procuring surrogates or to otherwise arrange or induce intended parents and surrogates to enter into surrogacy contracts in this Commonwealth. A violation of this section shall be punishable as a Class 1 misdemeanor.

B. Any person who acts as a surrogate broker in violation of this section shall, in addition, be liable to all the parties to the purported surrogacy contract in a total amount equal to three times the amount of compensation to have been paid to the broker pursuant to the contract . . .

C. The provisions of this section shall not apply to the services of an attorney in giving legal advice or in preparing a surrogacy contract.\(^{22}\)

In 2005, Illinois passed the Gestational Surrogacy Act, which establishes guidelines for how surrogacy arrangements are to be regulated in the state. The act sets forth requirements for both the surrogate and intended parents, as well as contract requirements. For example, in order to be a gestational surrogate in Illinois, a woman must be 21 years of age and have given birth to at least one child, completed a medical and mental health evaluation, undergone legal consultation with independent legal counsel, and obtained health insurance.\(^{23}\) The intended parents must contribute at least one of the gametes\(^ {24}\) resulting in the pre-embryo to be implanted in the surrogate and have a medical need for the gestational surrogacy, completed a mental health evaluation, and undergone legal consultation with independent legal counsel.\(^ {25}\) Under the act, a gestational surrogacy contract is enforceable if the following requirements are met:

- The contract is in writing;
- The contract is executed prior to the commencement of any medical procedures;
- All parties are represented by separate counsel in all matters concerning the surrogacy and the surrogacy contract;
- All parties have signed a written acknowledgment that he or she received information about the legal, financial, and contractual rights, expectations, penalties, and obligations of the contract;
- If the contract provides for the payment of compensation to the surrogate, the compensation is placed in escrow with an independent escrow agent; and
- The contract is witnessed by two competent adults.\(^ {26}\)

\(^{20}\) Behm, *supra* note 3, at 601.

\(^{21}\) N.H. REV. STAT. s. 168-B:16.

\(^{22}\) VA. CODE ANN. s. 20-165.

\(^{23}\) 750 ILL. COMP. STAT. 47/20.

\(^{24}\) A gamete refers to sperm and eggs. Specifically, a gamete is “[a] reproductive cell having the haploid number of chromosomes, especially a sperm or egg capable of fusing with a gamete of the opposite sex to produce a fertilized egg.” *Stedman’s Medical Dictionary* 324 (2002).

\(^{25}\) 750 ILL. COMP. STAT. 47/20.

\(^{26}\) Id. at 47/25.
Although not required to be enforceable, the gestational surrogacy contract may also contain additional provisions, such as any agreement by the intended parents to pay the gestational surrogate reasonable compensation or to pay for or reimburse the surrogate for reasonable expenses. As long as the parties follow the requirements set forth in the Gestational Surrogacy Act, parental rights automatically vest to the intended parents immediately upon the birth of the child.27

The National Conference of Commissioners on Uniform State Laws (Conference) has offered two model laws for guidance to states considering surrogacy: the Uniform Status of Children of Assisted Conception Act (USCACA) and the Uniform Parentage Act (UPA). The USCACA was not drafted to be a regulatory act, but rather its purpose is to protect the security and well-being of children born of assisted reproductive technologies.28 The USCACA has two alternative provisions applicable to surrogacy agreements: one that allows surrogacy agreements approved by a court (alternative A) and one that makes all surrogacy agreements void and unenforceable (alternative B).29 Only two states have adopted the USCACA: Virginia adopted alternative A to the USCACA, and North Dakota adopted alternative B.30 In 1973, the Conference proposed the UPA, which addressed the status of nonmarital children.31 The Conference promulgated a new UPA in 2000 to “create an updated uniform system of determining parentage in keeping with recent medical and technological advances in genetic testing and assisted reproduction.”32 The 2000 UPA permitted surrogacy agreements for married heterosexual couples and required a judicial hearing.33 In 2002, the UPA was amended to rescind the marriage provision.34 The 2000 UPA, as amended in 2002, supersedes previous uniform acts dealing with parentage, including the USCACA.35 As of 2005, only Texas and Utah had adopted the surrogacy provisions of the 2000 UPA.36

In 2008, the American Bar Association Section of Family Law’s Committee on Reproductive and Genetic Technology (Committee) ratified a model act governing assisted reproductive technology. The purpose of the model act is to give all parties associated with ART clear legal rights, obligations, and protections.37 The act covers topics such as informed consent, mental health consultations, privacy, embryo transfer and disposition, children of assisted reproduction, gestational agreements, payment to donors and carriers, health insurance, and quality assurance. For example, the act includes 12 informed consent requirements and seven required disclosures, ranging from disposition of preserved embryos to disclosure regarding embryo research.38 In the act, the Committee provided two options for legislation regulating gestational agreements. The first alternative provides for a court-involved approach, requiring all agreements to be approved by a judge prior to any action being taken.39 The National Conference of Commissioners on Uniform State Laws adopted a similar provision in 1988, which was included in the USCACA.40 However, this process appears to be time-consuming because it requires several court hearings prior to a birth certificate being issued, and it is also more costly due to the

27 Id. at 47/15(b).
29 Id. at s. 5.
32 Snyder and Byrn, supra note 30, at 652.
33 Benardo and Benardo, supra note 6, at 410.
34 Id.
35 Id.; see also UNIF. PARENTAGE ACT, supra note 31.
36 Benardo and Benardo, supra note 6, at 410.
38 Id. at Article 2.
39 Id. at Article 7.
multiple court requirements. According to the chairperson of the Committee, three states have adopted this alternative to gestational agreements, and two of the states have recognized infirmities with the process.\textsuperscript{41} The second alternative is an administrative model, taking the burden off the judiciary and placing it on the participating parties. It sets forth detailed steps that the parties must follow, and upon completion a birth certificate will be automatically issued to the intended parents. Illinois has a similar structure in place, and because of its success, the Committee added this alternative to the model act.\textsuperscript{42} The model act also provides guidance for payment to donors and gestational carriers. It provides that a donor may receive reimbursement for economic losses resulting from the retrieval or storage of gametes or embryos and that any consideration paid to a donor or gestational carrier must be reasonable and negotiated in good faith between the parties.\textsuperscript{43}

In its current form, the model act does not propose requirements that a person or business wishing to start an agency involved in ART must follow. However, the Committee is in the early stages of drafting amendments to the act that would address agency regulation.\textsuperscript{44} The model act has not yet been adopted by any state, although Illinois is considering its adoption.

**Federal Regulation**

Although several states have enacted legislation regulating surrogacy, problems still remain due to the lack of uniformity in state surrogacy legislation.\textsuperscript{45} Amid this lack of uniformity, Congress has attempted to regulate surrogacy on the federal level twice. The Surrogacy Arrangement Act of 1989 would have imposed criminal sanctions upon any person who “on a commercial basis knowingly makes, engages in, or brokers a surrogacy arrangement.”\textsuperscript{46} This bill died in the House Committee on Energy and Commerce. The second bill, titled Anti-Surrogate-Mother Act of 1989, would have criminalized commercial surrogacy.\textsuperscript{47} Specifically, the bill would have imposed criminal penalties upon anyone who:

- Procures or attempts to procure any woman to engage in surrogate motherhood;
- Provides medical assistance in carrying out an agreement to engage in surrogate motherhood;
- Advertises in or affecting interstate or foreign commerce any services in connection with surrogate motherhood;
- Being a U.S. citizen, engages outside the United States in any of the above conduct; or
- Sells for a profit the right to adopt a child or brokers such a sale.

The bill would have subjected surrogates, contracting parents, and third-party intermediaries to possible criminal penalties. The bill also contained an advertising ban, which subjected anyone who advertised the availability of commercial surrogacy services to criminal penalties. This bill died in the House Committee on Judiciary.

Currently, the only federal statute directly aimed at regulating assisted reproductive technologies is the Fertility Clinic Success Rate and Certification Act of 1992 (the Wyden Law), and its focus is on the medical aspects of ART.\textsuperscript{48} The Wyden Law serves two main purposes:

- To provide consumers with reliable and useful information about the efficacy of ART services offered by fertility clinics, and
- To provide states with a model certification process for embryo laboratories.\textsuperscript{49}
Under the Wyden Law, each ART program or clinic in the United States is required to annually report its rates of success to the Centers for Disease Control and Prevention (CDC). The Society for Assisted Reproductive Technology then validates the data through an auditing process. An ART program or clinic must only report its data to the CDC in order to satisfy the requirements of the law. If a program or clinic does not report, it is listed as “nonreporting” in the annual CDC publication; there are no other penalties for failure to report. The Wyden Law has been criticized for not having a financial penalty or imposing other sanctions for nonreporting; however, the CDC does not have the authority to impose sanctions or penalties. Research collected in 2005 indicated that more than 95 percent of ART programs or clinics report their results to the CDC.

The second purpose of the Wyden Law is to provide states with a model certification program for embryo laboratories. This program “is intended to provide a resource for states wishing to develop their own programs or for professional organizations seeking to develop guidelines or standards for embryo labs.” Adoption of the model program is voluntary, and only New York has adopted it.

**Professional Society Regulation**

The American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART), an affiliate of ASRM, are two of the most notable professional organizations for reproductive medicine. In order to be a member of ASRM, applicants must fill out an online application submitting their contact information, specialty, and education. There is also a form with questions that ASRM members are “requested respectfully” to answer concerning whether the person has ever been arrested for, charged with, or convicted of a felony or a misdemeanor, had a certificate of disqualification or license, had professional privileges at a healthcare facility revoked, or been denied a certificate of qualification or license. These organizations have propounded standards and guidelines for the practice of ART; however, both the ASRM’s system of professional self-regulation and SART membership are completely voluntary. According to research, approximately 85 to 95 percent of the ART programs or clinics in the United States are SART members. In order to be a SART member, an ART program or clinic must adhere to the propounded guidelines, its embryo laboratories must be certified, and it must comply with the reporting provisions of the Wyden Law.

The guidance from the ASRM comes in the form of published statements, opinions, and guidelines issued by its practice and ethics committees. The practice guidelines provide direction on subjects such as gamete and embryo donation, informed consent, number of embryos transferred, and preimplantation genetic diagnosis. The ethical guidelines have covered topics such as advertising, informed consent, and disposition of abandoned embryos. As stated previously, compliance with the ASRM guidelines is entirely voluntary.

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50 An ART program or clinic is defined as “a legal entity practicing under state law, recognizable to the consumer, that provides ART services to couples who have experienced infertility or are undergoing ART for other reasons.” *Id.* at 47-48.
51 *Id.* at 47-48.
53 *Id.*
54 President’s Council on Bioethics, *supra* note 49, at 50.
58 President’s Council on Bioethics, *supra* note 49, at 73.
61 *Id.* at 72-73.
Foreign Jurisdiction Regulation

The public policy considerations related to ART are not unique to the United States, as other countries have also explored options for regulating activities stemming from these technologies. In addition, ART can have international significance, as the costs associated with the technologies or the regulatory climate in one country may affect demand for ART in another country. A recent trend known as “reproductive tourism” has emerged, in which couples or individuals go to other countries for ART due to lower costs or less restrictive laws. For example, India does not currently have guidelines that address foreigners hiring Indian surrogates, which, combined with lower costs, has made it a popular country for couples to go to find a surrogate. The United States has also been on the receiving end of this “reproductive tourism,” in that many Canadians and Western Europeans come to the United States for ART because of increased regulations in their own countries.62

Although it has no direct legal effect on surrogacy regulation in the United States, Canada and England have attempted to regulate surrogacy. In 1982, the Attorney General for Ontario asked the Ontario Law Reform Commission (Ontario Commission) to look into the legal issues relating to surrogacy, among other forms of ART.63 One of the Ontario Commission’s recommendations was that no compensation to the surrogate should be allowed without prior judicial approval. The Ontario Commission reasoned that a judicial approval process may reveal any possible exploitation of the surrogate.64 Additionally, the Ontario Commission recognized that individuals may try to set up agencies that provide surrogacy services on a commercial basis. The Ontario Commission proposed that the Ministry of Community and Social Services be required to regulate such agencies that arrange surrogate agreements, by examining the credentials of the operators, the staff, the advertisement and recruitment practices, the services offered, and the fees charged.65

The framework developed by the Ontario Commission never became law in Canada. However, after additional studies were conducted,66 the Canadian legislature approved the Assisted Human Reproduction Act (AHRA) in 2004. The AHRA prohibits certain ART practices, including commercial surrogacy and the sale of gametes and embryos. Parties involved in a commercial surrogacy arrangement may be subject to criminal penalties of up to $500,000 in fines or 10 years in prison.67 The AHRA also established the Assisted Human Reproduction Agency of Canada, which “is responsible for licensing and monitoring all private and public fertility clinics, research facilities and other institutions whose research or commercial activity involves human gametes or embryos.”68

In 1982, the Committee of Inquiry into Human Fertilisation and Embryology (the Warnock Committee) was established in England to study emerging reproductive technologies.69 The Warnock Committee prepared a report (the Warnock Report) recommending a statutory licensing scheme to regulate infertility through the use of in vitro fertilization, artificial insemination by donor, and egg and embryo donation.70 Although the Warnock Report

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63. Behm, supra note 3, at 587.
64. Id. at 591.
65. Id. at 593.
66. In 1989, the Prime Minister created the Royal Commission on New Reproductive Technologies (Royal Commission) to address the medical, legal, economic, and ethical issues arising from new reproductive technologies. Id. at 594. The Royal Commission’s report recommended prohibiting commercial surrogacy. Specifically, it recommended that the government legislate “to prohibit receiving payment or any other financial or commercial benefit for acting as an intermediary, under threat of criminal sanction. It should also legislate to prohibit making payment for a preconception arrangement, under threat of criminal sanction.” Patrick Healy, Statutory Prohibitions and the Regulation of New Reproductive Technologies under Federal Law in Canada, 40 McGill L.J. 905, 934 (1995).
68. Galpern, supra note 14, at 18.
70. The Human Fertilisation and Embryology Authority (HFEA), established in 1990, “is responsible for the licensing and monitoring of all clinics offering IVF, donor insemination, and the storage of eggs, sperm and embryos.” The HFEA creates guidelines that clinics must follow and keeps a register of information about donors, treatments, and the children born from
approved these reproductive technologies, it recommended criminalizing both profit and non-profit organizations that recruit women to be surrogates. The Warnock Report resulted in the Surrogacy Arrangements Act of 1985 (the Act) in England. Section 2 of the Act states: “‘[n]o person shall on a commercial basis’ make, negotiate, or ‘compile any information with a view to its use in making, or negotiating the making of, surrogacy arrangements.’” The Act allows surrogates and the potential parents to negotiate directly or through an intermediary as long as the intermediary does not get paid. The Act only criminalizes the act of third parties making, negotiating, or facilitating surrogacy agreements for a fee.

Section 3 of the Act makes it a criminal offense to advertise the availability of a person to enter into a surrogacy agreement. It covers all forms of advertising, including advertising that does not originate in England, as long as the advertisements are intended to be received in England. This section applies to the surrogate, contracting parents, and intermediary agencies.

The legislative intent of the Act provides the following seven rationales for the prohibition against third-party intermediaries:

- There is exploitation of and risk to the surrogate.
- There is exploitation of and risk to the infertile couple.
- There is risk to the child.
- Selling children should be discouraged.
- The institution of the family is at risk.
- The moral fabric of society is at risk.
- Public opinion is against surrogacy.

One scholar’s primary criticism of England’s Act is that it left too many questions unanswered. For example, section 2 of the Act appears to be written broadly enough that it may discourage legal, medical, and psychological professionals from rendering help when surrogates and infertile couples request it. It has also been argued that section 3 of the Act, regarding the advertising ban, leaves only word-of-mouth communication as legal, which limits the amount of information available to those interested in surrogacy. In England, the Act has also caused the disappearance of organized surrogacy professionals to assist infertile couples.

**Licensing Schemes**

There are many similarities between adoption and assisted reproductive technologies. For example, both often originate with infertility, both involve facilitating parties in the reproductive process, such as agencies, and neither is nationally regulated. Because of the similarities, this report also looked at how parties come together in the adoption arena, as well as the licensing structure for certain adoption entities. In Florida, a child may be placed for adoption through an agency licensed by the state or through the use of an attorney serving as an intermediary. Both agencies and attorney intermediaries are within the statutory definition of an adoption entity.

Chapter 63, F.S., titled the Florida Adoption Act, provides a framework for regulating adoption in order to provide basic safeguards to all parties involved. Pursuant to the Florida Adoption Act, the Department of Children and Family Services (DCF or the department) is authorized to license “child welfare agencies that it determines to be qualified to place minors for adoption.” In Florida, it is unlawful for any person or agency, other than an

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71 Serratelli, *supra* note 69, at 643 (quoting Surrogacy Arrangements Act, ch. 49, s. 2(1) (1985)).

72 Id.

73 Id.

74 Id. at 644-45.

75 Id. at 646-49.

76 An “adoption entity” refers to the Department of Children and Family Services, a licensed child-placing agency, a child-caring agency, or an attorney. Section 63.032(3), F.S.

77 Section 63.202, F.S.
intermediary,\(^{78}\) to engage in the placement or adoption of children without a license from DCF.\(^ {79}\) In order to be licensed, an agency\(^ {80}\) must complete an application and go through a screening process.\(^ {81}\) After receiving an application for licensure, DCF conducts a licensing study, inspects the agency and the records of the agency, and interviews the applicant.\(^ {82}\) If an applicant meets the minimum licensing requirements, DCF will issue a license to a specific person or agency at a specific location. The license must be displayed in a conspicuous place and is valid for one year.\(^ {83}\) If a person or agency places a child without a license, or makes a willful or intentional misstatement on the license application or other required documentation, it is a misdemeanor of the first degree, and a third-degree felony for any subsequent violations.\(^ {84}\)

In addition to the licensing requirements, an agency must also maintain written personnel policies and procedures, including, for example, job descriptions and qualifications, salary scales and bonus procedures, employee benefits, provisions to encourage professional growth, and procedures for annual evaluations.\(^ {85}\) The department also adopted rules providing education requirements for personnel of a licensed child-placing agency. For example, the agency director must have a master’s degree in social work or a related area and at least two years’ experience in human services or child welfare programs.\(^ {86}\)

In terms of adoption-related fees, it is unlawful for any person, except an adoption entity, to charge or accept any fee or compensation for making a referral in connection with an adoption.\(^ {87}\) If the adoption entity is an agency, it may charge fees if they are approved by DCF and if they are for foster care expenses, pre- and post-placement social services, or agency facility and administrative costs. An adoption entity may also assess the following fees and costs:

- Reasonable living expenses of the birth mother, including rent, utilities, telephone service, food, toiletries, necessary clothing, transportation, insurance, and expenses found by the court to be necessary for the health and well-being of the birth mother and unborn child;
- Reasonable and necessary medical expenses;
- Expenses necessary to comply with the requirements of ch. 63, F.S.;
- Court filing expenses, court costs, and other litigation expenses and birth certificate and medical expenses;
- Costs associated with advertising; and
- Professional fees.\(^ {88}\)

Additionally, it is unlawful for any person, except an adoption entity, to advertise that a minor is available or sought for adoption, and it is unlawful for any person to publish or broadcast any such advertisement without including a Florida license number of the agency or attorney placing the advertisement.\(^ {89}\)

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\(^{78}\) An intermediary is defined as “an attorney who is licensed or authorized to practice in this state and who is placing or intends to place a child for adoption, including placing children born in another state with citizens of this state or country or placing children born in this state with citizens of another state or country.” Section 63.032(10), F.S.

\(^{79}\) See s. 409.175(4), F.S., and rule 65C-15.002, F.A.C.

\(^{80}\) An “agency” refers to a residential child-caring agency or a child-placing agency. Section 409.175(2), F.S., defines a child-placing agency as “any person, corporation, or agency, public or private, other than the parent or legal guardian of the child or an intermediary acting pursuant to chapter 63, that receives a child for placement and places or arranges for the placement of a child in a foster home, residential child-caring agency, or adoptive home.” A residential child-caring agency is defined as “any person, corporation, or agency, public or private, other than the child’s parent or legal guardian, that provides staffed 24-hour care for children in facilities maintained for that purposes, regardless of whether operated for profit or whether a fee is charged.” Examples of such child-caring agencies are: maternity homes, runaway shelters, group homes that are administered by an agency, emergency shelters, and wilderness camps.

\(^{81}\) Section 409.175(6), F.S.

\(^{82}\) Id. The statutory requirements for licensure are codified in s. 409.175(5), F.S.

\(^{83}\) Section 409.175(6), F.S.

\(^{84}\) Section 409.175(12), F.S.

\(^{85}\) Rule 65C-15.015, F.A.C.

\(^{86}\) Rule 65C-15.017, F.A.C.

\(^{87}\) Section 63.212(1)(f), F.S.

\(^{88}\) Section 63.097(2), F.S.
As another possible model for ART regulation, New York has a licensing scheme for persons involved in the procurement of organ, tissue, or body parts. Specifically, “[n]o person shall own or operate a bank or storage facility 90 that conducts procurement activity 91 in New York state unless a license has been issued.” 92 As part of the application process, an applicant must provide:

- The name of the operator, its officers, directors, principal stockholders, and controlling persons;
- A description of its organizational structure;
- The kind or kinds of procurement or storage services to be provided;
- The location and physical description of the bank or storage facility; and
- Other such information as the department may require. 93

Additionally, the New York Department of Health requires an applicant to complete a Disclosure of Ownership and Control Interest Statement, which includes questions such as: Has “the director . . . ever been convicted of a criminal offense related to the operation of a tissue bank, non-transplant anatomic bank, blood bank or clinical laboratory, including but not limited to any offense related to the furnishing of or billing for clinical laboratory services and medical care, services or supplies, or which is considered an offense involving theft or fraud?” 94

**Options and/or Recommendations**

Assisted reproductive technologies (ART) raise a number of policy considerations, and research has shown that jurisdictions around the country, and even the globe, have taken a variety of approaches to the regulation of ART. Some jurisdictions have chosen to regulate the number of embryos that can be implanted in a woman, and some have explored laws regarding embryo storage and research. The scientific or social aspects of ART, such as these examples, may be an area that the Legislature would like to study in the future; however, this report focuses primarily on the commercial component of ART, in particular the provision of third-party reproductive services on a commercial basis. Based upon a review of legal scholarship and discussions with industry representatives, multiple regulatory options exist to address this aspect of assisted reproductive technologies in Florida, if the Legislature chooses to do so.

**Licensing Scheme**

One option available to the Legislature is to pursue a regulatory licensing scheme for entities engaging in third-party reproductive services on a commercial basis. As noted in the Findings and Conclusions section of this report, a licensing scheme could include an application and screening process and possible criminal or administrative penalties for violations of the law. If the Legislature proposed a licensing scheme for ART agencies in Florida, it would need to identify a state agency to administer the licensing process and oversee enforcement. There would be a fiscal impact to the agency designated to license ART agencies; however, the exact fiscal impact may depend on the type of licensing scheme adopted.

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89 Section 63.212(1)(g), F.S.
90 A bank or storage facility refers to “any person or facility, which procures, stores or arranges for the storage of (a) non-transplant organs, or (b) tissue for transplantation, therapy, education, research, or fertilization purposes, including autologous procedures.” N.Y. PUBLIC HEALTH LAW s. 4360 (emphasis added).
91 Procurement activity is defined as “any activity which is necessary for the procurement of organs or tissue for transplantation, research, education, therapy, fertilization, or autologous purposes including solicitation, retrieval, donor selection and testing, clinical laboratory testing, including typing, preservation, transportation, allocation, distribution, storage, and payment activities.” N.Y. PUBLIC HEALTH LAW s. 4360 (emphasis added).
92 N.Y. PUBLIC HEALTH LAW s. 4364.
93 Id.
Statutory Requirements

Instead of creating a structured licensing scheme, the Legislature could choose to provide statutory requirements that a person or business that provides third-party reproductive services on a commercial basis must follow. For example, the Legislature could statutorily require that anyone who makes referrals relating to an egg, sperm, or preembryo donor or to a gestational surrogate use a third-party escrow account to hold all funds that are not for the benefit of the business or agency. Requiring a truly independent company to hold the money helps reduce the risk of situations arising in Florida similar to what happened when a California surrogacy agency allegedly embezzled money from prospective parents. Another possible element could be to require that the intended parents and the surrogate or donor, depending on the situation, be represented by independent counsel. The Legislature has already made this a statutory requirement when parties are involved in a preplanned adoption agreement. Section 63.213(4), F.S., provides that an “attorney who represents an intended father and intended mother or any other attorney with whom that attorney is associated shall not represent simultaneously a female who is or proposes to be a volunteer mother in any matter relating to a preplanned adoption agreement or preplanned adoption arrangement.” Examples of other possible statutory requirements would be to:

- Prohibit a person from engaging in third-party reproductive services on a commercial basis if he or she has any arrests, charges, or convictions relating to the practice of his or her profession, other health care related matters, third-party reimbursement, violence, moral turpitude, or controlled substances;
- Require agencies to perform child abuse and criminal background checks on donors and surrogates, as well as the intended parents;
- Require a written contract between the intended parents and the agency;
- Require gestational surrogacy contracts between the intended parents and the surrogate to be in writing;
- Establish a cap for donor and surrogate compensation and reimbursement;
- Require donors and surrogates to be U.S. citizens or permanent residents;
- Require agencies to have proof of informed consent from both parties; or
- Require agencies to have professional insurance coverage.

The Legislature has several options for enforcement of the statutory requirements. It could explicitly provide for a civil cause of action, so that if a person found that an ART agency was not following the requirements that person could bring a civil suit against the agency. The Legislature could also provide for the imposition of a civil penalty, such as a fine or injunction, against any party who violates the statute. The enforcing authority, named by the Legislature, would bring a court action in order to recover the civil penalty. Similar enforcement mechanisms are used by the Office of the Attorney General under the Florida Deceptive and Unfair Trade Practices Act (FDUTPA).\(^5\) \(^6\) Lastly, the Legislature could provide for criminal sanctions; however, prosecutors are given broad prosecutorial discretion\(^6\) in deciding whether to initiate and conduct criminal investigations, and it is not known how aggressive they would be in prosecuting violations of the statute. Arguably, depending on the type of illegal activity an agency is engaged in, prosecutors may already have the tools at their disposal to prosecute.

Advertising Regulations

Senate Bill 2640, from the 2009 Regular Session, provided that only an attorney may advertise or offer to the public in any manner or by any medium that an egg donor, sperm donor, preembryo donor, or gestational surrogate is available or is sought, and that any such advertisement must include the attorney’s Florida Bar number. This language raised several questions. For example, it was unclear what would happen if an organization in another state advertised nationally and its advertisement was aired in Florida. What if an out-of-state attorney advertised in Florida? Under the specific language of the bill, the advertisement must include a Florida Bar number.

\(^5\) See ss. 501.2075 and 501.211, F.S. The Legislature could prescribe enforcement mechanisms independently or it could specifically provide that violating the statute is a FDUTPA violation. Examples where the Legislature has cross-referenced FDUTPA can be found in ch. 400, F.S., dealing with nursing homes and related health care facilities; ch. 483, F.S., relating to health testing services; and ch. 559, F.S., relating to the regulation of trade, commerce, and investments. See ss. 400.464, 483.305, and 559.3906, F.S.

Although the advertising requirement proposed in SB 2640 had some unanswered questions, the Legislature has other possible alternatives. If the Legislature adopts a regulatory licensing scheme for agencies, it could require that the agency license number be included in all advertisements. If the Legislature proposes statutory requirements instead of a licensing scheme, then it could require an agency to include a statement in all advertisements that the agency is in full compliance with the statutory requirements. The Legislature could require an agency to include how many years it has been in business or whether it belongs to any professional organizations, such as the American Society for Reproductive Medicine. The Legislature could also require that agencies use accurate descriptors of their services, success rates, and fee structure in promotional materials.

No Action

The Legislature could choose to take no substantive action at this time and wait to see what the American Bar Association Section of Family Law’s Committee on Reproductive and Genetic Technology (Committee) puts forth as far as amendments to its model act with regard to ART agency regulation. However, the Committee is very early in this process, and it may take a few years before these amendments are available.

Statutory Clarification

Regardless of whether the Legislature chooses to adopt regulatory action at this time, or regardless of the type of action it does adopt, at a minimum Senate professional staff recommends that the Legislature consider clarifying certain provisions of existing law. First, the Legislature may wish to update ss. 742.11-742.17, F.S., by removing the term “commissioning couple.” As the law currently reads, only a commissioning couple can enter into a gestational surrogacy contract and have an expedited affirmation of parental status issued. If a single parent wishes to have a child using a surrogate, that person must legally adopt the child using a preplanned adoption agreement, even if the child shares genetic material with the single parent. One legal scholar noted that Florida’s current statutory language may be viewed as discriminatory and that:

> [s]ingle persons wishing to assert constitutional challenges against a legislative restriction limiting parenthood through surrogacy to married couples have two available arguments: (1) that such a restriction violates their fundamental right of privacy protected by the Due Process Clause of the Fourteenth Amendment because it infringes on their right to decide whether to bear or beget a child; and (2) that this legislative classification based on marital status is invidious discrimination which violates their rights under the Equal Protection Clause of the Fourteenth Amendment.

To date, it does not appear that there have been any constitutional challenges to the “commissioning couple” language in Florida’s statutory framework for gestational surrogacy. However, if the Legislature wishes to make a policy change, it may consider eliminating the term “commissioning couple” and replacing it with “intended parent.” Section 63.213, F.S., Florida’s preplanned adoption statute, also known as the traditional surrogacy statute, refers to the “intended mother” and the “intended father” but does not require the couple to be married.

Additionally, s. 742.14, F.S., makes reference to a preplanned adoption agreement, citing s. 63.212, F.S. However, the actual statutory reference for preplanned adoption agreements is s. 63.213, F.S. The Legislature may wish to correct this statutory reference.

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97 Section 742.13(2), F.S., defines a commissioning couple as “the intended mother and father of a child who will be conceived by means of assisted reproductive technology using the eggs or sperm of at least one of the intended parents.” In order for a gestational surrogacy contract to be valid, the commissioning couple must be legally married. See s. 742.15(1), F.S.

98 The process for entering a preplanned adoption agreement is set forth in s. 63.213, F.S.