# The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

	Pr	repared By:	The Profession	al Staff of the Comr	nittee on Rules	
BILL:	CS/CS/SB	698				
INTRODUCER:	Rules Committee; Criminal Justice Committee; and Senators Book and Stewart					
SUBJECT:	Reproductive Health					
DATE:	February 2	8, 2020	REVISED:			
ANALYST		STAFF DIRECTOR		REFERENCE	ACTION	
Davis		Cibula		JU	Favorable	
Stokes		Jones		CJ	Fav/CS	
. Davis		Phelps		RC	Fav/CS	

# Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

# I. Summary:

CS/CS/SB 698 establishes protections for people who are dealing with infertility and seek medical assistance to artificially conceive a child. In its broadest and most general terms, the bill requires donors, recipients, and facilities to enter into contracts that govern the use of reproductive materials, prohibits the misuse of those reproductive materials, and authorizes disciplinary actions and felony penalties for health care practitioners who intentionally transfer reproductive material into a recipient when the practitioner knows the recipient has not consented to the use of that reproductive material.

The bill creates s. 383.61, F.S., which requires a commissioning party or donor to contract with a donor bank, fertility clinic, or health care practitioner or reproductive storage facility before donating reproductive material. The contract must indicate what will be done with reproductive material that is not used.

This bill provides that by January 1, 2021, donor banks, fertility clinics, health care practitioners, and reproductive storage facilities must establish, and annually submit best practice policies, which are consistent with 42 U.S.C. part 263a(f), to the appropriate licensing agency for review. Donor banks, fertility clinics, health care practitioners, and reproductive storage facilities must clearly label reproductive material, comply with the terms of the contract, and maintain records for a minimum of 30 years. The bill expressly prohibits a health care practitioner from transferring or inseminating a recipient with the reproductive material of the health care practitioner.

This bill creates s. 784.086, F.S., establishing the crime of reproductive battery. It is a third degree felony for a health care practitioner to intentionally transfer into the body of a recipient the reproductive material of a donor that the recipient has not consented to. It is a second degree felony if the health care practitioner uses his or her own reproductive material, unless the recipient has provided written consent to the use of the health care practitioner's reproductive material.

This bill adds new grounds for the discipline of health care practitioners. A health care practitioner who intentionally transfers or inseminates, or causes a recipient to have transferred into her body or be inseminated with reproductive material of a donor without the recipient's consent, is subject to disciplinary action as provided in ss. 456.072, 458.331, or 459.015, F.S., as appropriate. The bill also provides for the immediate suspension of a license if a health care practitioner commits the crime of reproductive battery.

This bill creates s. 456.51, F.S., which provides that a health care practitioner must have written consent to perform a pelvic examination. A health care practitioner may conduct a pelvic examination without written consent if a court orders the performance of the examination for the collection of evidence, the examination is immediately necessary to avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function, or the exam is indicated in the standard of care for a procedure that the patient has consented to.

This bill may have an indeterminate fiscal impact on the licensing agency that annually reviews the best practices policies. Additionally, this bill may have a positive indeterminate prison bed impact (unquantifiable positive prison bed impact). See Section V. Fiscal Impact Statement.

This bill is effective July 1, 2020.

#### II. Present Situation:

The recent arrival of genetic testing kits and ancestry reports, such as Ancestry.com or 23andMe, has yielded unsettling results for many users. According to media reports, several fertility doctors who represented that they were using the sperm of a patient's husband or an anonymous donor to artificially inseminate a patient, were in fact lying to their patients. The fertility specialists were inseminating the patients with their own sperm. Even more distressing to the victims of these acts was the realization that the doctors' actions were not actually illegal.<sup>1</sup>

#### Fertility Specialists Alleged to Have Been Sperm Donors to their Patients

#### Virginia

One media report stated that Dr. Cecil Jacobson, a fertility specialist in Vienna, Virginia, may have secretly donated his own sperm to father at least 75 children. Although prosecutors wanted

<sup>&</sup>lt;sup>1</sup> Ellen Trachman, Above the Law, *Intense and Dramatic Testimony Propels Texas Fertility Fraud Bill Forward* (April 17, 2019), available at <a href="https://abovethelaw.com/2019/04/intense-and-dramatic-testimony-propels-texas-fertility-fraud-bill-forward/">https://abovethelaw.com/2019/04/intense-and-dramatic-testimony-propels-texas-fertility-fraud-bill-forward/</a> (last visited February 13, 2020) and CBS News, *Indiana Fertility Doctor Used Own Sperm to Impregnate Patients*, *Court Docs Say* (September 12, 2016), available at <a href="https://www.cbsnews.com/news/indiana-fertility-doctor-used-own-sperm-to-impregnate-women-court-docs-say/">https://www.cbsnews.com/news/indiana-fertility-doctor-used-own-sperm-to-impregnate-women-court-docs-say/</a> (last visited February 13, 2020).

to try Dr. Jacobson for lying to patients about the source of the sperm, no laws at that time prohibited a doctor from donating sperm to a patient. Instead, prosecutors charged him with the more basic counts of criminal fraud in his medical practice which involved the use of telephones and the United States Postal Service. He was convicted of committing 52 counts of fraud and perjury in 1992.<sup>2</sup>

#### Connecticut

A doctor in Greenwich, Connecticut, Ben D. Ramaley, settled a lawsuit in 2009 for secretly using his own sperm to impregnate a patient. The case was settled without any depositions being taken, but a gag order was issued which prevented the plaintiffs from discussing the case.<sup>3</sup>

When Barbara Rousseau used genetic testing to learn who her biological father was, she was astounded to learn that her father was actually her mother's fertility specialist in 1977, not an anonymous sperm donor. Barbara's parents filed a fertility fraud lawsuit against Dr. John Boyd Coats of Berlin, Vermont, in December, 2018, and seek compensatory and exemplary damages. The suit alleges that the doctor's conduct was "outrageously reprehensible" and had the character of outrage that is often "associated with a crime" and was done with malice.<sup>4</sup>

#### Indiana

In 2018, Dr. Ronald Cline of Zionsville, Indiana, surrendered his medical license after pleading guilty to two counts of obstruction of justice. It was alleged that he inseminated dozens of women with his own sperm while telling his patients that the donors were anonymous men. DNA tests revealed that he is likely the father of as many as 46 children whose mothers were his patients. Indiana law, at that time, did not specifically prohibit fertility specialists from donating their own sperm.<sup>5, 6</sup>

#### Colorado

Dr. Paul Brennan Jones, a fertility specialist in Grand Junction, Colorado, was sued in October, 2019, for using his own sperm, rather than the sperm of anonymous donors, to impregnate women. Maia Emmons-Boring, whose mother relied on Dr. Jones for fertility treatment nearly 40 years earlier, has learned though DNA testing that she and her sister have five known half-siblings who were fathered by Dr. Jones. Ms. Emmons-Boring has been contacted by three

<sup>&</sup>lt;sup>2</sup> Doctor Is Found Guilty in Fertility Case, N.Y. TIMES (March 5, 1992), available at <a href="https://perma.cc/J2NA-NUY8">https://perma.cc/J2NA-NUY8</a> (last visited February 14, 2020), cited by Jody Lynee Madeira, infra at Note 4.

<sup>&</sup>lt;sup>3</sup> LeAnne Gendreau and Diana Perez, NBC Connecticut News, *Fertility Doc Accused of Making His Own Donation* (November 12, 2009) NBC News, available at <a href="https://www.nbcconnecticut.com/news/local/fertility-doctor-may-have-done-the-deed-himself/2060754/">https://www.nbcconnecticut.com/news/local/fertility-doctor-may-have-done-the-deed-himself/2060754/</a> (last visited February 13, 2020).

<sup>&</sup>lt;sup>4</sup> Jody Lynee Madeira, *Understanding Illicit Insemination and Fertility Fraud, From Patient Experience to Legal Reform,* Columbia Journal of Gender & Law, 2019 Fall Issue 110, 123-124.

<sup>&</sup>lt;sup>5</sup> Associated Press, Fertility Doctor Who Used Own Sperm to Impregnate Women Surrenders License (August 23, 2018), available at <a href="https://nypost.com/2018/08/23/fertility-doctor-who-used-own-sperm-to-impregnate-women-surrenders-license/">https://nypost.com/2018/08/23/fertility-doctor-who-used-own-sperm-to-impregnate-women-surrenders-license/</a> (last visited February 13, 2020).

<sup>&</sup>lt;sup>6</sup> Associated Press, *Indiana Senate Sends Sperm-Misuse Legislation to Governor* (April 17, 2019), available at <a href="https://www.ibj.com/articles/73357-indiana-senate-sends-sperm-misuse-legislation-to-governor">https://www.ibj.com/articles/73357-indiana-senate-sends-sperm-misuse-legislation-to-governor</a> (last visited February 13, 2020).

additional people who are biologically linked to them through DNA testing. The civil lawsuit against the doctor alleges negligence, fraud, and other claims for damages.<sup>7</sup>

#### Idaho

In 2019, Dr. Gerald Mortimer, a retired gynecologist in Idaho Falls, Idaho, admitted to using his own sperm to impregnate multiple women in his infertility practice. He left the Obstetrics and Gynecology Associates practice in Idaho Falls because he feared he would be caught using his own sperm to impregnate women. At least one lawsuit is pending against him.<sup>8</sup>

# The Difficulty of Holding the Doctors Legally Accountable

Holding the fertility doctors legally accountable for their fraudulent acts, either criminally or civilly, has been difficult. One of the most obvious obstacles is an expired statute of limitation because the fraudulent act often occurred decades before it was discovered. Another obstacle involves the destruction of evidence which could be the destruction of medical records. It is difficult to prosecute a case criminally as a traditional sexual assault case because the women "consented" to the inseminations. It is difficult to prevail in a civil case because the facts do not readily lend themselves to the elements of fraud. The fraudulent inseminations more closely resemble "fraud in the inducement" where a person agrees to a procedure knowing what is involved, but consents to the procedure based upon false representations made by the defendant doctor.<sup>9</sup>

# Several States' Responses to Fertility Fraud

#### **Texas**

In response to the revelation that the doctors' actions were not technically illegal, several states have enacted laws to criminalize the doctors' deceptive acts. Texas, for example, enacted a law in 2019 that creates a sexual assault felony, punishable by up to 2 years' imprisonment, if a health care services provider, while performing an assisted reproduction procedure, uses human reproductive material from a donor knowing that the recipient has not expressly consented to the use of the material from that donor. Additionally, and because most children born under these fraudulent circumstances and their parents do not discover the truth of their conception until many years later, victims are given 2 years from the time the offense is discovered to bring an action for the crime of sexual assault. The act is prospective in its application. <sup>10</sup>

<sup>&</sup>lt;sup>7</sup> Morgan Phillips, Fox News, *Colorado fertility doctor used his own sperm to impregnate women, lawsuit claims* (October 29, 2019), available at <a href="https://www.foxnews.com/us/colorado-fertility-doctor-used-his-own-sperm-to-impregnate-women-lawsuit-claims">https://www.foxnews.com/us/colorado-fertility-doctor-used-his-own-sperm-to-impregnate-women-lawsuit-claims</a> (last visited February 13, 2020).

<sup>&</sup>lt;sup>8</sup> Grace Hansen, EastIdahoNews.com, Former Idaho Falls Doctor Admits to Using Own Sperm to Inseminate Multiple Patients (November 7, 2019), available at <a href="https://www.eastidahonews.com/2019/11/former-idaho-falls-gynecologist-admits-to-using-own-sperm-to-father-patients-children/">https://www.eastidahonews.com/2019/11/former-idaho-falls-gynecologist-admits-to-using-own-sperm-to-father-patients-children/</a> (last visited February 13, 2020).

<sup>&</sup>lt;sup>9</sup> Supra, Note 4 at 113, 184.

<sup>&</sup>lt;sup>10</sup> Texas SB 1259 (2019), available at <a href="https://capitol.texas.gov/BillLookup/Text.aspx?LegSess=86R&Bill=SB1259">https://capitol.texas.gov/BillLookup/Text.aspx?LegSess=86R&Bill=SB1259</a> (last visited February 13, 2020).

## California

California passed legislation in 2011 that criminalized the use of sperm, ova, or embryos in assisted reproduction technology for a purpose other than that indicated by the provider. A violator will be punished by imprisonment between 3 and 5 years and a fine that does not exceed \$50,000.<sup>11</sup>

#### Indiana

Indiana similarly enacted legislation in 2019. The statute establishes a cause of action for civil fertility fraud and provides that a prevailing plaintiff may receive compensatory and punitive damages or liquidated damages of \$10,000. The legal action must be commenced within 10 years of the child's 18th birthday, 20 years after the procedure was performed, when the person first discovers evidence through DNA testing, when the person becomes aware of a record that provides sufficient evidence to bring a suit against the defendant, or when the defendant confesses to the offense. <sup>12</sup>

## **Colorado**

Colorado is now considering a bill entitled "Misuse of Human Reproductive Material" which creates a new civil cause of action as well as a criminal offense if a health care provider, during the course of assisted reproduction, uses a donation from someone without obtaining the written consent of the patient. The bill provides for compensatory or liquidated damages of \$50,000 in a civil action and provides a felony penalty for the criminal act. Conviction of the offense is also considered unprofessional conduct under the licensing statute.<sup>13</sup>

#### Additional States Considering Legislation

Nebraska, Ohio, and Washington state are currently considering legislation to provide redress against physicians for fertility fraud.

#### Florida Law

It does not appear that Florida law specifically prohibits a health care practitioner from inseminating a patient with reproductive material from a donor without the patient's consent. As discussed above, the statute of limitations, the time allowed to bring an action for a previous act, has generally expired because many people do not realize that fraud was committed until decades after the insemination. Similarly, it would be challenging to prove sexual battery because the patient "consented" to the insemination, and the act was not technically committed against her will.

<sup>&</sup>lt;sup>11</sup> California Penal Code s. 367g., available at <a href="https://california.public.law/codes/ca">https://california.public.law/codes/ca</a> penal code section 367g (last visited February 13, 2020).

<sup>&</sup>lt;sup>12</sup> Senate Enrolled Act No. 174, an act amending the Indiana Code concerning civil procedure, available at <a href="http://iga.in.gov/legislative/2019/bills/senate/174#document-d66c4e90">http://iga.in.gov/legislative/2019/bills/senate/174#document-d66c4e90</a> (last visited February 13, 2020).

<sup>&</sup>lt;sup>13</sup> HB 20-1014, Colorado General Assembly, Second Regular Session, 72nd General Assembly, available at <a href="https://www.leg.colorado.gov/bills/hb20-1014">https://www.leg.colorado.gov/bills/hb20-1014</a> (last visited February 13, 2020).

# Fertility Clinics in Florida

As far as staff has been able to determine, no current law requires donor banks or fertility clinics to be regulated, registered, or inspected in the state. According to the DOH, there are approximately 30 fertility clinics operating in the state, some with multiple locations, and four donor banks.<sup>14</sup>

## **Licensing and Penalties**

#### Health Care Practitioners

The DOH's Division of Medical Quality Assurance (MQA) has regulatory authority over health care practitioners. <sup>15</sup> MQA works in conjunction with 22 boards and 4 councils to license and regulate 7 types of health care facilities and more than 40 health care professions. <sup>16</sup> Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory and licensure authority for MQA.

Section 456.072, F.S., authorizes a regulatory board or DOH, if there is no board, to discipline a health care practitioner for a number of offenses, including but not limited to:

- Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.
- Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or scheme in or related to the practice of a profession.
- Engaging or attempting to engage in sexual misconduct as defined in s. 456.063, F.S.

If it is found that a licensee committed a violation, the board or DOH may impose penalties, including but not limited to:<sup>17</sup>

- Refuse to certify, or to certify with restrictions, an application for a license.
- Suspend or permanently revoke a license.
- Impose an administrative fine.
- Issue a reprimand or letter of concern.
- Place the licensee on probation.

The board or DOH, if there is no board, must consider what is necessary to protect the public or to compensate the patient when it decides the penalty to impose.<sup>18</sup>

<sup>&</sup>lt;sup>14</sup> Florida Department of Health, *SB 698 Legislative Bill Analysis*, (February 7, 2020) (on file with the Senate Committee on Criminal Justice).

<sup>&</sup>lt;sup>15</sup> Section 456.001(4), F.S., provides that "health care practitioners," include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.

<sup>&</sup>lt;sup>16</sup> Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2018-2019*, available at <a href="http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/\_documents/annual-report-1819.pdf">http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/\_documents/annual-report-1819.pdf</a> (last visited February 18, 2020).

<sup>&</sup>lt;sup>17</sup> Section 456.072(2), F.S.

<sup>&</sup>lt;sup>18</sup> *Id*.

Section 456.074(1), F.S., authorizes the Department of Health to issue an emergency order to suspend a license when someone pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to, regardless of adjudication, certain felonies and misdemeanors.

# Physicians - Allopathic and Osteopathic

Florida licenses both allopathic and osteopathic physicians. Allopathic physicians diagnose, treat, operate, or prescribe for any human disease, pain, injury, deformity, or other physical or mental condition. <sup>19</sup> The scope of practice for osteopathic physicians is the same as that of allopathic physicians; however, osteopathic medicine emphasizes the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health. <sup>20</sup>

# <u> Allopathic – Chapter 458</u>

Chapter 458, F.S., governs licensure and regulation of the practice of medicine by the Florida Board of Medicine (allopathic board) in conjunction with the DOH. The chapter provides, among other things, licensure requirements. An individual seeking to be licensed as an allopathic physician, must meet certain statutory requirements, including that he or she must not have committed an act or offense that would constitute a basis for disciplining a physician pursuant to s. 458.331, F.S.

Section 458.331, F.S., provides grounds for disciplinary action for allopathic physicians. An allopathic physician may be denied a license or disciplined<sup>21</sup> for certain acts, including, but not limited to:

- Attempting to obtain, obtaining, or renewing a license to practice medicine by bribery, fraudulent misrepresentation, or through an error of the DOH or the board.
- Being convicted or found guilty of, or entering a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the practice of medicine or the ability to practice medicine.
- False, deceptive, or misleading advertising.
- Making deceptive, untrue, or fraudulent representations in or related to the practice of medicine or employing a trick or scheme in the practice of medicine.<sup>22</sup>

#### Osteopathic – Chapter 459

Chapter 459, F.S., governs licensure and regulation of the practice of medicine by the Florida Board of Osteopathic Medicine (osteopathic board), in conjunction the DOH. The chapter provides, among other things, licensure requirements.

<sup>&</sup>lt;sup>19</sup> Section 458.305, F.S.

<sup>&</sup>lt;sup>20</sup> Section 459.003, F.S.

<sup>&</sup>lt;sup>21</sup> Section 458.331, F.S., provides that physicians found in violation of this section are subject to the penalties provided in s. 456.072(2), F.S.

<sup>&</sup>lt;sup>22</sup> Section 458.331, F.S.

Section 459.015, F.S., provides grounds for disciplinary actions for osteopathic physicians. An osteopathic physician may be denied a license or disciplined<sup>23</sup> for certain acts, including, but not limited to:

- Attempting to obtain, obtaining, or renewing a license to practice medicine by bribery, fraudulent misrepresentation, or through an error of the DOH or the board.
- Being convicted or found guilty of, or entering a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the practice of medicine or the ability to practice medicine.
- Failing to perform a statutory or legal obligation placed upon a licensed osteopathic physician.
- Fraudulently altering or destroying records relating to patient care or treatment, including, but not limited to, patient histories, examination results, and test results.<sup>24</sup>

#### Clinics

Chapter 400, F.S., governs the licensure and regulation of health care clinics. The chapter provides, among other things, licensing requirements. A license must be obtained by the AHCA to operate a clinic.<sup>25</sup>

Section 400.995, F.S., provides the administrative penalties that the AHCA may impose for a violation of statute or Rule. Administrative penalties, include, but are not limited to:

- Denial of the application for license renewal.
- Revoke and suspend the license.
- Impose administrative fines.<sup>26</sup>

# Florida Requirements for Informed Consent

The only general law in Florida on informed consent,<sup>27</sup> appears in ch. 766, F.S., Medical Malpractice and Related matters.<sup>28</sup> However, Florida physicians and physicians practicing within a postgraduate training program approved by the Board of Medicine must explain the medical or surgical procedure to be performed to the patient and obtain the informed consent of the patient. However, the physician does not have to obtain or witness the signature of the patient on the written form evidencing informed consent.<sup>29</sup>

<sup>&</sup>lt;sup>23</sup> Section 459.015, F.S., provides that physicians found in violation of this section are subject to the penalties provided in s. 456.072(2), F.S.

<sup>&</sup>lt;sup>24</sup> Section 459.015, F.S.

<sup>&</sup>lt;sup>25</sup> Section 400.991, F.S.

<sup>&</sup>lt;sup>26</sup> Section 400.995, F.S.

<sup>&</sup>lt;sup>27</sup> Informed consent is a process in which a health care provider educates a patient about the risks, benefits, and alternatives of a procedure or intervention. *See* William Gossman, Imani Thornton, John Hipskind, *Informed Consent*, (July 2019), available at <a href="https://www.ncbi.nlm.nih.gov/books/NBK430827/">https://www.ncbi.nlm.nih.gov/books/NBK430827/</a> (last visited February 18, 2020).

<sup>&</sup>lt;sup>28</sup> Section 766.103, F.S., provides generally that no recovery will be allowed against a health care practitioner when informed consent was obtained in accordance with an accepted standard of medical practice and a reasonable person would have an understanding of the procedure from the information that was provided, or the patient would reasonably, under all the circumstances, have undergone the procedure had the health care practitioner obtained informed consent in accordance with the accepted standard of medical practice.

<sup>&</sup>lt;sup>29</sup> Rule 64B8-9.007, F.A.C.

#### Pelvic Examinations

A pelvic examination involves the visual examination of the external genitalia and an internal visual examination of the vaginal walls and cervix using a speculum and palpation of the pelvic organs.<sup>30</sup> Health care practitioners often perform pelvic examinations as a part of the annual well woman visit.<sup>31</sup> A health care practitioner may also perform a pelvic examination to diagnose specific health conditions, such as cancer and bacterial vaginosis.<sup>32</sup>

The American College of Obstetricians and Gynecologists finds that data is currently insufficient to make a recommendation for or against routine pelvic examinations.<sup>33</sup> Therefore, it recommends that pelvic examinations be performed when indicated by medical history or symptoms, such as abnormal bleeding, pelvic pain, or urinary issues.<sup>34</sup>

#### Pelvic Examinations on Unconscious or Anesthetized Patients

In recent years, articles have detailed reports of medical students performing pelvic examinations, without consent, on women who are anesthetized or unconscious, a practice that has been common since the late 1800's. <sup>35</sup> In 2003, a study reported that 90 percent of medical students who completed obstetrics and gynecology rotations at four Philadelphia-area hospitals performed pelvic examinations on anesthetized patients for educational purposes. <sup>36</sup>

Several medical organizations have taken positions that pelvic examinations should not be performed on anesthetized or incapacitated patients, including:

• The American Medical Association Council on Ethical and Judicial Affairs recommends that in situations where the patient will be temporarily incapacitated (e.g., anesthetized) and

<sup>&</sup>lt;sup>30</sup> A pelvic examination usually involves an examination of a woman's vulva, vagina, uterus, ovaries, and fallopian tubes. It may also include examination of the bladder and the rectum. *See* Melissa Conrad Stoppler, MD, MedicineNet, *Pelvic Exam*, available at <a href="https://www.medicinenet.com/pelvic exam/article.htm#why is a pelvic exam performed">https://www.medicinenet.com/pelvic exam/article.htm#why is a pelvic exam performed</a> (last visited February 18, 2020).

<sup>&</sup>lt;sup>31</sup> Amir Qaseem, et al., *Screening Pelvic Examination in Adult Women: A Clinical Practice Guideline from the American College of Physicians*, 161 Ann Intern Med 67 (July 2014), available at <a href="https://annals.org/aim/fullarticle/1884537/screening-pelvic-examination-adult-women-clinical-practice-guideline-from-american?ga=2.7498674.1663533724.1580510917-1215329083.1580510917">https://annals.org/aim/fullarticle/1884537/screening-pelvic-examination-adult-women-clinical-practice-guideline-from-american?ga=2.7498674.1663533724.1580510917-1215329083.1580510917</a> (last visited February 18, 2020).

<sup>&</sup>lt;sup>32</sup> *Id*.

 $<sup>^{33}</sup>$  *Id*.

<sup>&</sup>lt;sup>34</sup> *Id*.

<sup>35</sup> See: Paul Hsieh, Pelvic Exams on Anesthetized Women Without Consent: A Troubling and Outdated Practice, FORBES (May 14, 2018), available at <a href="https://www.forbes.com/sites/paulhsieh/2018/05/14/pelvic-exams-on-anesthetized-women-without-consent-a-troubling-and-outdated-practice/#74d152df7846">https://www.forbes.com/sites/paulhsieh/2018/05/14/pelvic-exams-on-anesthetized-women-without-consent-a-troubling-and-outdated-practice/#74d152df7846</a> (last visited February 18, 2020); Dr. Jennifer Tsai, Medical Students Regularly Practice Pelvic Exams on Unconscious Patients. Should They?, ELLE (June 24, 2019), available at <a href="https://www.elle.com/life-love/a28125604/nonconsensual-pelvic-exams-teaching-hospitals/">https://www.elle.com/life-love/a28125604/nonconsensual-pelvic-exams-teaching-hospitals/</a> (last visited February 18, 2020); Lorelei Laird, Pelvic Exams Performed without Patients' Permission Spur New Legislation, ABA JOURNAL (September 2019), available at <a href="https://www.abajournal.com/magazine/article/examined-while-unconscious">https://www.abajournal.com/magazine/article/examined-while-unconscious</a> (last visited February 18, 2020); and Amanda Eisenberg, New Bills Would Ban Pelvic Exams without Consent, POLITICO (March 14, 2019), available at <a href="https://www.politico.com/states/new-york/albany/story/2019/03/13/new-bills-would-ban-pelvic-exams-without-consent-910976">https://www.politico.com/states/new-york/albany/story/2019/03/13/new-bills-would-ban-pelvic-exams-without-consent-910976</a> (last visited February 18, 2020).

<sup>&</sup>lt;sup>36</sup> John Duncan, Dan Luginbill, Matthew Richardson, Robin Fretwell Wilson, *Using Tort Law to Secure Patient Dignity: Often Used as Teaching Tools for Medical Students, Unauthorized Pelvic Exams Erode Patient Rights, Litigation Can Reinstate Them*, 40 TRIAL 42 (October 2004).

where student involvement is anticipated, involvement should be discussed before the procedure is undertaken whenever possible.<sup>37</sup>

- The Committee on Ethics of the American College of Obstetricians and Gynecologists resolved that "pelvic examinations on an anesthetized woman that offer her no personal benefit and are performed solely for teaching purposes should be performed only with her specific informed consent obtained before her surgery."<sup>38</sup>
- The Association of American Medical Colleges reversing its prior policy position, offered that "performing pelvic examinations on women under anesthesia, without their knowledge or approval ... is unethical and unacceptable."<sup>39</sup>

California, Hawaii, Illinois, Iowa, Maryland, Oregon, Utah, and Virginia prohibit unauthorized pelvic examinations.<sup>40</sup>

# III. Effect of Proposed Changes:

# Section 1 – Definitions, Contract Requirements, and Best Practices

This bill creates s. 383.61, F.S., which requires a commissioning party or donor to enter in to a written contract before donating reproductive material and requires the establishment of best practices for the use of assisted reproductive technology.

## **Definitions**

The bill defines the following terms:

- "Assisted reproductive technology" means those procreative procedures that involve the storage or laboratory handling of human eggs, pre-embryos, or sperm, including, but not limited to, in vitro fertilization embryo transfer, gamete intrafallopian transfer, pronuclear state transfer, tubal embryo transfer, and zygote intrafallopian transfer.
- "Commissioning party" means the intended parent or parents of a child who will be conceived by means of assisted reproductive technology.
- "Donor" means a person who donates reproductive material, regardless of whether for personal use or compensation.
- "Donor bank" means any facility that collects reproductive material from donors for use by a fertility clinic.
- "Egg" means the unfertilized female reproductive cell.

<sup>&</sup>lt;sup>37</sup> AMA Council on Ethical and Judicial Affairs, *Medical Student Involvement in Patient Care: Report of the Council on Ethical and Judicial Affairs*, AMA Journal of Ethics (March 2001), available at <a href="https://journalofethics.ama-assn.org/article/medical-student-involvement-patient-care-report-council-ethical-and-judicial-affairs/2001-03">https://journalofethics.ama-assn.org/article/medical-student-involvement-patient-care-report-council-ethical-and-judicial-affairs/2001-03</a> (last visited February 18, 2020).

<sup>&</sup>lt;sup>38</sup> American College of Obstetricians and Gynecologists, Committee on Ethics, *Professional Responsibilities in Obstetric-Gynecologic Medical Education and Training*, (August 2011), available at <a href="https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/Professional-Responsibilities-in-Obstetric-Gynecologic-Medical-Education-and-Training?IsMobileSet=false</a> (last visited February 18, 2020).

<sup>&</sup>lt;sup>39</sup> Robin Fretwell Wilson, *Autonomy Suspended: Using Female Patients to Teach Intimate Exams Without Their Knowledge or Consent*, 8 J of Health Care Law and Policy 240, available at <a href="https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=880120">https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=880120</a> (last visited February 18, 2020).

<sup>&</sup>lt;sup>40</sup> Lorelei Laird, *Pelvic Exams Performed without Patients' Permission Spur New Legislation*, ABA JOURNAL (September 2019), available at <a href="http://www.abajournal.com/magazine/article/examined-while-unconscious">http://www.abajournal.com/magazine/article/examined-while-unconscious</a> (last visited February 18, 2020).

• "Fertility clinic" means a facility in which reproductive materials are subject to assisted reproductive technology for the purpose of being transferred into the body of a recipient.

- "Health care practitioner" has the same meaning as provided in s. 456.001, F.S.
- "Preembryo" means the product of fertilization of an egg by a sperm until the appearance of the embryonic axis.
- "Recipient" means a person who has a donor's reproductive material transferred into her body.
- "Reproductive material" means any human "egg," "preembryo," or "sperm."
- "Reproductive storage facility" means a facility in which reproductive materials are stored until they are transferred into the body of a recipient using assisted reproductive technology.
- "Sperm" means the male reproductive cell.

# **Contract Requirements**

Additionally, s. 383.61, F.S., requires a commissioning party or donor to contract with a donor bank, fertility clinic, health care practitioner, or reproductive storage facility before donating reproductive material. At a minimum, the contract must indicate what must be done with the reproductive material if:

- The donor dies or becomes incapacitated;
- A designated recipient for the donation dies or becomes incapacitated;
- The commissioning party separate or their marriage is dissolved;
- One member of the commissioning party dies or becomes incapacitated;
- The reproductive material is unused, including whether it may be disposed of, offered to a different recipient, or donated to science; and
- Any other unforeseen circumstance occurs.

The above-named entities must ensure that each donation is clearly labeled according to the terms of the contract and must ensure that the donation is transferred, returned, disposed of, or stored according to the terms of the contract.

#### **Best Practice Policies**

This bill provides that by January 1, 2021, donor banks, fertility clinics, health care practitioners, and reproductive storage facilities must establish, and annually submit best practices, which are consistent with 42 U.S.C. part 263a(f), to the appropriate licensing agency or department for review. Donor banks, fertility clinics, health care practitioners, and reproductive storage facilities must clearly label reproductive material, comply with the terms of the contract, and maintain records for a minimum of 30 years. The bill expressly prohibits a health care practitioner from transferring or inseminating a recipient or causing a recipient to have transferred into her body or be inseminated with the reproductive material of the health care practitioner.

# Sections 2, 3, 5, and 6 – Disciplinary Actions and the Immediate Suspension of a License

This bill amends ss. 456.072, 458.331, or 459.015, F.S., to add new grounds for discipline of health care practitioners. Health care practitioners who intentionally transfer into or inseminate a recipient with, or cause a recipient to have transferred into her body or be inseminated with the health care practitioner's reproductive material, or is found in violation of the contract or best

practice policies, including proper labeling and maintenance of records, are subject to penalties provided in ss. 456.072, 458.331, or 459.015, F.S., as appropriate.

The bill amends section 456.074(1), F.S., to require the Department of Health to issue an emergency order suspending the license of a practitioner who pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to reproductive battery.

# **Section 7 – Reproductive Battery**

This bill creates s. 784.086, F.S., establishing the crime of reproductive battery. It is a third degree felony<sup>41</sup> for a health care practitioner to intentionally transfer into the body of a recipient the reproductive material of a donor or any object containing the reproductive material of a donor, knowing that the recipient has not consented to the use of the material of that donor. It is a second degree felony<sup>42</sup> if the health care practitioner uses his or her own reproductive material, unless the recipient has provided written consent to the use of the health care practitioner's reproductive material.

The statute of limitations for a third or second degree felony is generally three years.<sup>43</sup> The bill provides that the statute of limitations for reproductive battery does not begin to run until the violation is discovered and reported to law enforcement or any other governmental agency. It is not a defense to the crime of reproductive battery that the recipient consented to an anonymous donor.

#### Section 4 – Pelvic Examinations

This bill creates s. 456.51, F.S., providing that a health care practitioner must have the written consent of a patient or a patient's legal representative to perform a pelvic examination. A health care practitioner may conduct a pelvic examination without written consent if:

- A court orders the performance of the examination for the collection of evidence;
- The examination is immediately necessary to avert a serious risk of imminent, substantial, and irreversible physical impairment of a major bodily function; or
- The examination is indicated in the standard care for a procedure that the patient has consented to.

This bill is effective July 1, 2020.

# IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

<sup>&</sup>lt;sup>41</sup> A third degree felony is punishable by up to five years in state prison and a fine not exceeding \$5,000. Sections 775.082 and 775.083, F.S.

<sup>&</sup>lt;sup>42</sup> A second degree felony is punishable by up to 15 years in state prison and a fine not exceeding \$10,000. Sections 775.082 and 775.083, F.S.

<sup>&</sup>lt;sup>43</sup> Section 775.15(2)(b), F.S.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None identified.

# V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

This bill creates a third degree felony for a health care practitioner to intentionally transfer into the body of a recipient the reproductive material of a donor knowing that the recipient has not consented to the use of that donor's reproductive material. It is a second degree felony if the health care practitioner uses his or her own reproductive material, unless the recipient provides written consent. Because this bill creates new crimes, it may have a positive indeterminate prison bed impact (unquantifiable positive prison bed impact).

Additionally, this bill may have an indeterminate fiscal impact on the DOH or the appropriate licensing agency for reviewing best practice policies and implementing disciplinary action for violations.

#### VI. Technical Deficiencies:

The bill appears to contradict itself on the issue of whether a health care practitioner may be a donor of reproductive material. Section 7, provides that a health care practitioner is not subject to criminal penalties for being a donor if the recipient provides written consent for the use of the health care practitioner's reproductive material. However, section 1 prohibits, without exception, from transferring his or her reproductive material into any recipient.

## VII. Related Issues:

None.

#### VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 383.61, 456.51, and 784.086.

This bill substantially amends the following sections of the Florida Statutes: 456.072, 456.074, 458.331, and 459.015.

#### IX. Additional Information:

# A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

# CS/CS by Rules on February 26, 2020:

The committee substitute refines the provisions of the underlying bill by:

- Expanding the bill's purposes and requirements to include reproductive storage facilities.
- Removing the authority for AHCA to perform annual inspections of donor banks and fertility clinics.
- Revising provisions in the bill that relate to consent for pelvic examinations.
- Allowing the use of a health care practitioner's reproductive material only when the recipient provides written consent.

#### CS by Criminal Justice on February 18, 2020:

The committee substitute:

- Defines the terms, "assisted reproductive technology," "commissioning party," "donor," "donor bank," "egg," "fertility clinic," "health care practitioner," "preembryo," "recipient," "reproductive material," and "sperm."
- Requires a commissioning party or donor of reproductive material to enter into a
  contract with a donor bank, fertility clinic, or health care practitioner, and provides
  for minimum contract requirements.
- Requires that donor banks, fertility clinics, and health care practitioners establish best practice policies, consistent with federal law. Additionally, requirements for labeling and maintenance of records is provided in the bill.
- Expressly prohibits a health care practitioner from inseminating or implanting a recipient with the reproductive material of the health care practitioner.
- Requires the AHCA to annually inspect all donor banks and fertility clinics.
- Provides penalties when donor banks, fertility clinics or health care professionals are found in violation of the best practices.
- Creates the crime of reproductive battery. It is a third degree felony for a health care practitioner to intentionally penetrate the vagina of a recipient with the reproductive material of a donor that the patient has not consented to. It is a second degree felony if the health care practitioner uses his or her own reproductive material.
- Requires a health care practitioner to obtain written consent to perform a pelvic exam.

R	Amendme	nts:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.