OHIO LEGISLATIVE SERVICE COMMISSION

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Office of Research and Drafting

Legislative Budget Office

H.B. 502
135th General Assembly

Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. Somani and Piccolantonio

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SUMMARY

Prohibition on designating personhood

- Prohibits human reproductive material that exists outside of a human uterus from being connoted as or designated a person.

Regulation of assisted reproduction

- Prohibits any Ohio political subdivision, or official or employee of Ohio, from prohibiting or limiting any of the following:
  - An individual from accessing, continuing, or completing assisted reproduction or using or controlling the use of the individual's human reproductive material.
  - Any assisted reproduction health care provider from performing assisted reproduction treatments or procedures or providing information;
  - Any insurance provider from covering assisted reproduction treatments or procedures.
- Establishes a cause of action for violating the prohibition.

Qualified immunity for assisted reproduction

- Grants qualified immunity from civil liability, criminal liability, and professional discipline to a health care provider or reproductive health care helper for providing reproductive health care and to an individual for seeking reproductive health care.
- Specifies that the qualified immunity does not apply if the act or omission constitutes willful or wanton misconduct or reckless disregard for the consequences.

Informed consent for assisted reproduction

- Requires health care providers to obtain informed consent before performing or providing assisted reproduction health care.

Data privacy for assisted reproduction or donor information

- Prohibits, generally, a regulated entity from collecting, retaining, using, or disclosing personal assisted reproduction or donor information, including disclosure to third parties such as other states and law enforcement.
- Establishes civil causes of action for individuals and the Ohio Attorney General against regulated entities who fail to comply with the bill's requirements or violate its prohibitions.

Protection of patient records from out-of-state third parties

- Prohibits a health care provider or facility from being required or compelled to provide patient records to any out-of-state third party.

TABLE OF CONTENTS

Prohibition on designating personhood 2
Regulation of assisted reproduction 3
Prohibition on banning or limiting access 3
Civil action 3
Qualified immunity for assisted reproduction 4
Assisted reproduction definitions 5
Informed consent for assisted reproduction 6
Data privacy for assisted reproduction and donation 6
Data restrictions 6
Mechanisms to access and delete data 6
Privacy policy 7
Enforcement mechanisms 8
Individual civil action 8
Unfair or deceptive act or practice 9
Data privacy definitions 9
Protection of patient records from out-of-state third party 12

DETAILED ANALYSIS

Prohibition on designating personhood

The bill prohibits, for purposes of the Revised Code and notwithstanding any other provision of law, human reproductive material that exists outside of a human uterus from being

considered an unborn human individual, an unborn child, a fetus, a natural person, or any other term that connotes or designates personhood.[1]

Regulation of assisted reproduction

Prohibition on banning or limiting access

Under the bill, no Ohio political subdivision, or state official or employee, may prohibit or unreasonably limit, for reasons other than to enforce health and safety regulations, any of the following:

- Any individual from doing any of the following:
  - Accessing assisted reproduction;
  - Continuing or completing an ongoing assisted reproduction treatment or procedure pursuant to a written plan or agreement with an assisted reproduction health care provider;
  - Using or controlling the use of the individual's human reproductive material.
- Any assisted reproduction health care provider from doing either of the following:
  - Performing assisted reproduction treatments or procedures;
  - Providing evidence-based information related to assisted reproduction.
- Any insurance provider from covering assisted reproduction treatments or procedures.

Nothing in the bill may be construed as preempting any written agreement or contract regarding an individual's human reproductive material.

The bill defines "assisted reproduction health care provider" as any entity or individual, including any physician, nurse practitioner, physician assistant, or pharmacist, who is engaged or seeks to engage in assisted reproduction care, such as through the provision of evidence-based information, counseling, or items and services related to fertility treatment.[2]

Civil action

The bill allows all of the following to bring a civil action against any Ohio political subdivision, or state official or employee, for the violation of, or the enactment, implementation, or enforcement of a limitation or requirement that violates the prohibition described above:

- The Attorney General;
- Any individual or entity adversely affected by the violation;

[1] R.C. 3732.13.

[2] R.C. 3732.08.

- An assisted reproduction health care provider on the provider's own behalf, on behalf of the provider's staff, and on behalf of the provider's patients who are or may be adversely affected by the violation.

The court may award appropriate equitable relief, including temporary, preliminary, or permanent injunctive relief. It must award the costs of litigation and reasonable attorney's fees to any prevailing plaintiff. A plaintiff is not liable to a defendant for costs or attorney's fees in any nonfrivolous action filed under the bill.

Notwithstanding any other provision of law, no Ohio political subdivision, or state official or employee, is immune from an action brought for violation of the prohibition in a court of competent jurisdiction. This means that existing laws that provide sovereign immunity would not apply in the circumstances covered by the bill.

Nothing in the bill can be construed to do either of the following:

- Prohibit the enforcement of health and safety regulations that apply to assisted reproduction health care providers or health care facilities that provide assisted reproduction care, if the regulations do both of the following:
  - Advance the safety of health care services or the health of patients;
  - Cannot be advanced by a less restrictive alternative measure or action.
- Modify, supersede, or otherwise affect any law regarding insurance coverage of assisted reproduction.[3]

Qualified immunity for assisted reproduction

The bill grants qualified immunity to health care providers providing assisted reproduction care, health care facilities where assisted reproduction care is provided, individuals seeking assisted reproduction care (including donors), and assisted reproduction care helpers. The bill specifies that, except as otherwise provided in continuing laws related to fraudulent assisted reproduction or assisted reproduction performed without consent,[4] the health care provider, health care facility, individual, or helper is not liable for or subject to damages in a civil action, prosecution in a criminal proceeding, or professional disciplinary action for any of the following:

- A claim of injury to or death of any human reproductive material as an unborn human individual;
- Providing, accessing, or utilizing assisted reproduction care.

The bill's immunity does not apply if the act or omission associated with providing assisted reproduction care constitutes negligence, willful or wanton misconduct, or reckless

[3] R.C. 3732.09.

[4] R.C. 2907.13, 2907.14, 4731.861, and 4731.864, not in the bill.

disregard for loss to person or property or the consequences so as to affect the life or health of the patient. Further, nothing in bill may be construed to permit a wrongful death action related to a loss of human reproductive material.[5]

Assisted reproduction definitions

The bill defines the following terms:

- "Assisted reproduction" is a method of causing pregnancy other than through sexual intercourse, including all of the following:
  - Intrauterine insemination;
  - Human reproductive material donation;
  - In vitro fertilization and transfer of embryos;
  - Intracytoplasmic sperm injection.
- "Assisted reproductive care" is medical, surgical, counseling, or referral services that are lawful in Ohio or the receipt of products relating to assisted reproduction that is lawful in Ohio, including services, procedures, or medicines relating to assisted reproduction and the provision of human reproductive material by a donor.
- "Assisted reproduction care helper" is a person who facilitates or otherwise has supported or is supporting an individual in seeking or receiving assisted reproduction care in Ohio, including a person who provides funding, lodging, transportation, doula services, information, data sharing services such as electronic medical records programs, or other financial or practical support to an individual seeking or receiving assisted reproduction care.
- "Donor" is an individual who provides human reproductive material to a health care professional to be used for assisted reproduction, regardless of whether the human reproductive material is provided for consideration. The term does not include any of the following:
  - A husband or a wife who provides human reproductive material to be used for assisted reproduction by the wife;
  - A woman who gives birth to a child by means of assisted reproduction;
  - An unmarried man who, with the intent to be the father of the resulting child, provides human reproductive material to be used for assisted reproduction by an unmarried woman.
- "Health care provider" is an advanced practice registered nurse, a registered nurse, a pharmacist, a dentist, an optometrist, a physician, a physician assistant, or a hospital.

[5] R.C. 2305.2312(B) and (C).

- "Human reproductive material" means:
  - Human spermatozoa or ova;
  - A human organism at any stage of development from fertilized ovum to embryo.[6]

Informed consent for assisted reproduction

Under the bill, assisted reproduction health care can be performed or provided only if the assisted reproduction health care provider has obtained each patient's informed consent. The provider must provide each patient with written copies of the provider's and health care facility's assisted reproduction-related policies and services applicable to the patient. Each patient must sign a form acknowledging that the patient has received the information and consents to the policies and applicable services.[7]

Data privacy for assisted reproduction and donation

The bill adds new privacy protections related to personal assisted reproduction or donor information that apply to entities that are not covered under current state and federal laws that protect patient health information.

Data restrictions

Under the bill, a regulated entity may not collect, retain, use, or disclose personal assisted reproduction or donor information, except in either of the following circumstances:

- With the express consent of the individual to whom the information relates;
- As is strictly necessary to provide a product or service that the individual has requested.

The regulated entity must restrict access to personal assisted reproduction or donor information to its employees or service providers for which access is necessary to provide a requested product or service to the individual.

For purposes of compliance with the bill's data restriction requirements by a service provider of a regulated entity, a request from an individual to the regulated entity for a product or service, and an express consent from the individual to the regulated entity, must be treated as also having been provided to the service provider.[8]

Mechanisms to access and delete data

The bill requires a regulated entity to make available a reasonable mechanism by which an individual, upon a verified request, may do the following:

1. Access both of the following:

[6] R.C. 2305.2312(A); R.C. 2305.2311 and 2907.13, not in the bill.

[7] R.C. 3732.14.

[8] R.C. 3732.02.

a. The individual's personal assisted reproduction or donor information that is retained by the regulated entity, including how and from which third parties the regulated entity collected any information about the individual and information that the regulated entity inferred about the individual;

b. A list of the third parties to which the regulated entity disclosed the individual's personal assisted reproduction or donor information.

2. Request the deletion of any retained personal assisted reproduction or donor information related to the individual, including any information that the entity collected from a third party or inferred from other retained information.

The information described in (1) above must be made available in both a human-readable format and a structured, interoperable, and machine-readable format. The regulated entity is required to comply with a verified request without undue delay, but no later than 15 days after the date the verified request was received. The entity cannot charge the individual a fee for the request.

Nothing in the bill's provisions may be construed to require a regulated entity to do any of the following:

- Take an action that would convert information that is not personal information into personal information;
- Collect or retain personal information that the regulated entity would otherwise not collect or retain;
- Retain personal information longer than the regulated entity would otherwise retain the information.

The bill defines "reasonable mechanism," with respect to a regulated entity and a right described under (2) above, as a mechanism to which both of the following apply:

- Is equivalent in availability and ease of use to that of other mechanisms for communicating or interacting with the regulated entity;
- Includes an online means of exercising the right described under (2) above.[9]

Privacy policy

Under the bill, a regulated entity must maintain a privacy policy relating to the entity's practices regarding the collecting, retaining, using, and disclosing of personal assisted reproduction or donor information. If the entity has a website, it must prominently publish the privacy policy on its website. The privacy policy must be clear and conspicuous and include all of the following:

[9] R.C. 3732.03.

- A description of the entity's practices regarding the collecting, retaining, using, and disclosing of personal assisted reproduction or donor information;
- A clear and concise statement of the categories of the information collected, retained, used, or disclosed;
- A clear and concise statement of the entity's purposes for the collecting, retaining, using, or disclosing of the information;
- A list of the specific third parties to which the entity discloses the information, and a clear and concise statement of the purposes for disclosing the information, including how the information may be used by each third party;
- A list of the specific third parties from which the entity has collected the information, and a clear and concise statement of the purposes for which the information is collected;
- A clear and concise statement describing the extent to which individuals may exercise control over the collecting, retaining, using, and disclosing of personal assisted reproduction or donor information, and the steps an individual must take to implement control;
- A clear and concise statement describing the efforts of the entity to protect personal assisted reproduction or donor information from unauthorized disclosure.[10]

Enforcement mechanisms

Individual civil action

The bill allows any individual alleging a violation of its provisions governing data privacy to bring a civil action in any court of competent jurisdiction. If the individual prevails, the court may award the following:

- $100 to $1,000 per violation per day, or actual damages, whichever is greater;
- Punitive damages;
- Reasonable attorneys' fees and litigation costs;
- Any other relief, including equitable or declaratory relief, that the court determines appropriate.

A violation of the bill's data privacy requirements constitutes a concrete and particularized injury in fact to the individual to whom the information relates. No pre-dispute arbitration agreement or pre-dispute joint-action waiver is valid or enforceable with respect to a dispute arising from a data privacy violation. Any determination as to whether or how the bill's provision governing pre-dispute arbitration agreements and joint-action waivers applies

[10] R.C. 3732.04.

must be made by a court, rather than an arbitrator, without regard to whether the agreement purports to delegate the determination to an arbitrator.

The bill defines the following terms for purposes of its individual civil action provisions:

- "Pre-dispute arbitration agreement" is any agreement to arbitrate a dispute that has not arisen at the time of the making of the agreement.
- "Pre-dispute joint-action waiver" means an agreement that would prohibit a party from participating in a joint, class, or collective action in a judicial, arbitral, administrative, or other forum, concerning a dispute that has not yet arisen at the time the agreement is made.[11]

Unfair or deceptive act or practice

The bill additionally provides that a violation of the bill's data privacy requirements is an unfair or deceptive act or practice in violation of Ohio's existing Consumer Sales Practices Act. The Attorney General is required to ensure compliance with the bill's data privacy requirements in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are applicable for violations of the Consumer Sales Practices Act. The Attorney General may adopt related rules in accordance with the Administrative Procedure Act.[12]

A person injured by a violation of the bill's data privacy requirements has a cause of action and is entitled to the same relief available to a consumer under the Consumer Sales Practices Act.[13]

Data privacy definitions

The bill defines the following terms:

- "Collect" means for a regulated entity to obtain personal assisted reproduction or donor information in any manner.
- "Commerce" means commerce among the several states or with foreign nations, or in any territory of the United States or in the District of Columbia, or between any such territory and another, or between any such territory and any state or foreign nation, or between the District of Columbia and any state or territory or foreign nation.[14]
- "Disclose" means for a regulated entity to release, transfer, sell, provide access to, license, or divulge personal assisted reproduction or donor information in any manner to a third party, including the federal government, the state, any political subdivision, or a law enforcement agency.

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[11] R.C. 3732.05.

[12] R.C. 3732.06; R.C. 1345.02 to 1345.13, not in the bill.

[13] See R.C. 1345.09, not in the bill.

[14] "Federal Trade Commission Act," 15 United States Code (U.S.C.) 44, not in the bill.

- "Express consent" means informed, opt-in, voluntary, specific, and unambiguous written consent, including by electronic means, to collecting, retaining, using, or disclosing personal assisted reproduction or donor information.

  "Express consent" does not include any of the following:

  - Consent secured without first providing to the individual a clear and conspicuous disclosure, apart from any privacy policy, terms of service, terms of use, general release, user agreement, or other similar document, of all information material to the provision of consent;
  - Hovering over, muting, pausing, or closing a given piece of content;
  - Agreement obtained through the use of a user interface designed or manipulated with the substantial effect of subverting or impairing user autonomy, decision-making, or choice.

- "Personal information" means information that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly to, a particular individual.

- "Personal assisted reproduction or donor information" means personal information relating to the past, present, or future use of assisted reproduction by an individual or the past, present, or future provision of human reproductive material by a donor, including any of the following:

  - Efforts to research or obtain assisted reproduction-related or donor-related information, services, or supplies, including location information that might indicate an attempt to acquire or receive such information, services, or supplies;
  - Provision of human reproductive material by a donor or the use of human reproductive material for assisted reproduction;
  - Fertility-related conditions, status, diseases, or diagnoses, including pregnancy, menstruation, ovulation, the use of assisted reproduction procedures, and the ability to conceive a pregnancy, regardless of whether the individual is sexually active, and whether the individual is engaging in unprotected sex;
  - Fertility-related or assisted reproduction-related surgeries or procedures;
  - Use or purchase of any medication related to fertility, including medicine for assisted reproduction;
  - Bodily functions, vital signs, measurements, or symptoms related to menstruation or pregnancy, such as basal temperature, cramps, bodily discharge, or hormone levels;
  - Any information about diagnoses or diagnostic testing, treatment, medications, or the use of any product or service relating to the matters described above;
  - Any information described above that is derived or extrapolated from nonhealth information, including proxy, derivative, inferred, emergent, or algorithmic data.

- "Regulated entity" means any entity, to the extent the entity is engaged in activities in or affecting commerce, that is either:
  - A person, partnership, or corporation subject to the jurisdiction of the Federal Trade Commission;
  - Notwithstanding federal law governing the Commission's powers to investigate and prevent certain entities from using unfair or deceptive methods to affect commerce[15] or any jurisdictional limitation of the Commission, either of the following:
    - A common carrier subject to the "Communications Act of 1934";[16]
    - An organization not organized to carry on business for its own profit or that of its members.

  "Regulated entity" does not include any of the following:
  - A covered entity or business associate under the HIPAA privacy regulations;[17]
  - An entity that is subject to records disclosure restrictions under the "Public Health Service Act."[18]
- "Service provider" means a person to whom both of the following apply:
  - Collects, retains, uses, or discloses personal assisted reproduction or donor information for the sole purpose of, and only to the extent that the person is, conducting business activities on behalf of, for the benefit of, under instruction of, and under contractual agreement with a regulated entity and not any other individual or entity;
  - Does not divulge personal assisted reproduction or donor information to any individual or entity other than the regulated entity or a contractor to the service provider bound to information processing terms not less restrictive than terms to which the service provider is bound.

A person shall only be considered a service provider in the course of the collection, retention, use, or disclosure activities described above.

- "Third party" means any person who is not any of the following:
  - The regulated entity that is disclosing or collecting personal assisted reproduction or donor information;

[15] Section 4, 5(a)(2), or 6 of the "Federal Trade Commission Act," 15 U.S.C. 44; 45(a)(2); and 46, not in the bill.

[16] 47 U.S.C. 151 *et seq.*

[17] Section 1180(b)(3) of the "Social Security Act," 42 U.S.C. 1320d-9(b)(3).

[18] Section 543 of the "Public Health Service Act," 42 U.S.C. 290dd-2.

- The individual to whom the personal assisted reproduction or donor information relates;
- A service provider.[19]

Protection of patient records from out-of-state third party

Under the bill, no assisted reproduction health care provider or health care facility that provides assisted reproduction care may be required or compelled to provide patient records to any out-of-state third party, including the federal government, another state, any political subdivision, or a law enforcement agency.

The bill defines "health care facility" as a hospital, clinic, ambulatory surgical treatment center, other center, medical school, office of a physician, infirmary, dispensary, medical training institution, or other institution or location in or at which medical care, treatment, or diagnosis is provided to a person.[20]

HISTORY

Action	Date
Introduced	04-22-24

ANHB0502IN-135/ts

[19] R.C. 3732.01.

[20] R.C. 3732.11; R.C. 2925.11, not in the bill.