

2023 -- H 5177

=====
LC000773
=====

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2023

—————
A N A C T

RELATING TO HEALTH AND SAFETY -- EMBRYO SAFETY AND STORAGE

Introduced By: Representatives McNamara, Shallcross Smith, Alzate, Casimiro,
Donovan, Kazarian, Morales, and Felix

Date Introduced: January 19, 2023

Referred To: House Health & Human Services

It is enacted by the General Assembly as follows:

1 SECTION 1. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby
2 amended by adding thereto the following chapter:

3 CHAPTER 13.8

4 EMBRYO SAFETY AND STORAGE ACT OF 2023

5 **23-13.8-1. Title.**

6 This act shall be known as and may be cited as the “Embryo Safety and Storage Act of
7 2023.”

8 **23-13.8-2. Findings.**

9 The general assembly finds as follows:

10 (1) In vitro fertilization, commonly known as IVF, is a widely used method of assisted
11 reproductive technology (ART). ART has helped an estimated six million (6,000,000) couples in
12 the United States who have trouble getting or maintaining a pregnancy start families.

13 (2) IVF provides a pathway for people to parenthood.

14 (3) It is in the best interest of the people of this state to direct the department of health to
15 promulgate rules and regulations governing the storage of human eggs, pre-embryos, and embryos
16 in embryo storage facilities to guard against catastrophic storage system failure and the potential
17 loss of such specimens that may result from long-term power outages during storms and other
18 natural disasters.

19 **23-13.8-3. Definitions.**

1 As used in this chapter, the following terms shall have the following meanings, unless the
2 context clearly indicates otherwise:

3 (1) "Department" means the Rhode Island department of health.

4 (2) "Director" means the director of the Rhode Island department of health.

5 (3) "Embryo storage facility" means a facility which cryopreserves and stores human eggs,
6 pre-embryos, and embryos for later use in in vitro fertilization, embryo transfer, gamete transfer,
7 pronuclear stage transfer and zygote transfer, and other procedures performed to achieve a
8 pregnancy or pregnancies. Embryo storage facility shall also include the office of a licensed health
9 care provider which stores human eggs, pre-embryos, or embryos.

10 (4) "Person" means any individual, corporation, company, association, organization,
11 society, firm, partnership, joint stock company, or the state or any political subdivision thereof.

12 **23-13.8-4. Prohibited activities.**

13 (a) No person shall conduct, maintain, or operate an embryo storage facility in this state
14 unless licensed by the department pursuant to the provisions of this chapter. A separate license shall
15 be required for each embryo storage facility location. The license shall be posted and displayed at
16 all times in a prominent location within the facility. No license issued pursuant to this chapter shall
17 be transferable. A change in the ownership of the facility shall require notification to the department
18 within fourteen (14) calendar days and reapplication for licensure.

19 (b) The department shall not license a person to conduct, maintain, or operate an embryo
20 storage facility pursuant to this chapter unless the department is satisfied that the person has
21 demonstrated good character, competency, and integrity, and has furnished such information to the
22 director as the director may require for this purpose.

23 **23-13.8-5. Rules and regulations.**

24 (a) The department shall promulgate rules and regulations governing the storage and care
25 of human eggs, pre-embryos, and embryos by an embryo storage facility in accordance with:

26 (1) Standards ISO 9001 and ISO 20387 of the International Organization for
27 Standardization;

28 (2) Standards for biorepositories established by the College of American Pathologists
29 Biorepository Accreditation Program; and

30 (3) The U.S. Food and Drug Administration guidance on current good tissue practices.

31 (b) The rules and regulations authorized by this section shall promote safety and best
32 practices among embryo storage facilities and, at a minimum prescribe standards governing the
33 operation, maintenance, and administration of embryo storage facilities the safety and adequacy of
34 the physical plant or the facilities compliance with state and local fire safety codes the number of

1 staff and the qualifications of each staff member, the protection and safety of the equipment used
2 by embryo storage facilities to process and store human eggs, pre-embryos, and embryos, the
3 maintenance and confidentiality of records and furnishing of required information, the maintenance
4 of all appropriate accreditations and the establishment of a quality management program the review
5 of the scope of internal audits.

6 (c) The department shall conduct an on-site facility inspection and shall evaluate the
7 embryo storage facility to determine whether the facility complies with the provisions of this
8 chapter.

9 (d) The department shall have the authority to inspect and examine the physical plant or
10 facilities of an embryo storage facility and to inspect all documents, records, files, or other data
11 maintained pursuant to this chapter during normal operating hours and without prior notice.

12 (e) The department shall request the appropriate state and local fire, health, and building
13 officials to conduct examinations and inspections to determine compliance with state and local
14 ordinances, codes, and regulations by an embryo storage facility. The inspections shall be
15 conducted and the results reported to the department within sixty (60) days after the request.

16 (f) If an embryo storage facility meets the requirements of this chapter and the rules and
17 regulations promulgated hereunder, the department shall issue a license to the facility. A license
18 shall be valid for a period of one year and may be renewed at the end of that period, subject to
19 continued compliance with the provisions of this of this chapter.

20 (g) All rules and regulations promulgated pursuant to this chapter shall be adopted and
21 amended in accordance with chapter 35 of title 42 ("administrative procedures").

22 **23-13.8-6. Licensing of active facilities.**

23 (a) Any person operating an embryo storage facility on or after the effective date of this
24 chapter or desiring to operate an embryo storage facility shall make application for licensure in the
25 manner and on the forms prescribed by the director. The license application form shall include, but
26 shall not be limited to, the following information:

27 (1) The name and address of the embryo storage facility, the operator of the facility, and
28 the staff;

29 (2) The qualifications of the staff members, each member of the board of directors of the
30 corporation, and the embryo storage facility operator; a description of the facility's premises and
31 facilities and the hours of its operation; and

32 (3) Any other information the director deems necessary to include on the license
33 application form.

34 (b) If an embryo storage facility meets the requirements of this chapter and of the rules and

1 regulations promulgated hereunder, the department shall issue a license to the facility. A license
2 shall be valid for a period of one year and may be renewed at the end of that period, subject to
3 continued compliance with the provisions of this chapter.

4 **23-13.8-7. Fees.**

5 (a) The director shall establish a minimum fee to be paid by each embryo storage facility
6 at the time of application for a license and at every renewal of a license.

7 (b) The income received from licensure and renewal fees pursuant to this section shall be
8 appropriated to the department to effectuate the purposes of this chapter.

9 **23-13.8-8. License revocation.**

10 The department may deny, suspend, revoke, or refuse to renew a license for good cause,
11 including, but not limited to:

12 (1) Failure of an embryo storage facility or its operator to comply with the provisions of
13 this chapter;

14 (2) Violation of the terms and conditions of a license by an embryo storage facility or its
15 operator;

16 (3) Use of fraud or misrepresentation by an embryo storage facility or its operator in
17 obtaining a license or in the subsequent operation of the facility;

18 (4) Refusal by an embryo storage facility or its operator to furnish the department with
19 required files, reports, or records; or

20 (5) Refusal by an embryo storage facility or its operator to permit an inspection by an
21 authorized representative of the department during normal operating hours.

22 **23-13.8-9. Hearings.**

23 (a) The department, before denying, suspending, revoking, or refusing to renew a license,
24 shall give notice to the operator personally, or by certified or registered mail to the last known
25 address of the operator with return receipt requested. The notice shall afford the operator with an
26 opportunity to be heard in person or by an attorney, and to offer evidence pertinent to the subject
27 of the hearing.

28 (b) The hearing shall take place within sixty (60) days from the issuance or mailing of the
29 notice and shall be conducted in accordance with chapter 35 of title 42 ("administrative
30 procedures").

31 **23-13.8-10. Acting without a license.**

32 Any person who operates or assists in the operation of an embryo storage facility which
33 does not have a license, who has used fraud or misrepresentation in obtaining a license or in the
34 subsequent operation of a facility, who offers, advertises, or provides any service not authorized by

1 a valid license, or who violates any other provision of this chapter shall be guilty of a felony and
2 upon conviction thereof, shall be subject to a fine of up to five thousand dollars (\$5,000), or
3 imprisonment for a period of up to two (2) years, or both.

4 SECTION 2. This act shall take effect on January 1, 2024

=====
LC000773
=====

EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

A N A C T
RELATING TO HEALTH AND SAFETY -- EMBRYO SAFETY AND STORAGE

1 This act would create the “Embryo Safety and Storage Act of 2023.” The act would require
2 the department of health to regulate and license embryo storage facilities.

3 This act would take effect on January 1, 2024.

=====
LC000773
=====