

CHAPTER 268

AN ACT concerning the regulation and licensure of embryo storage facilities and supplementing Title 26 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

C.26:2A-23 Findings, declarations relative to embryo storage facilities.

1. The Legislature finds and declares that:

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

b. In 2016, the federal Centers for Disease Control and Prevention reported that there were approximately 267,000 IVF cycles performed in the United States, with more than five percent of those cycles occurring in New Jersey. By the end of the century, more than a million American patients who suffer from infertility will undergo IVF procedures.

c. The use of ART in the United States is not as prevalent as its use in other developed countries. In Japan, one in 20 children are born as a result of ART. In Norway the number is one in 10. As more women rise to executive positions in America's board rooms, and IVF becomes a more financially viable option because of increased health insurance coverage, ART will provide more of an opportunity for couples to preserve their fertility until they are ready to start a family.

d. IVF provides a pathway to motherhood for women who have experienced life threatening diseases, such as cancer, and the reproductive damage that is often a consequence of the treatments associated with these illnesses.

e. While technological advances in, and success rates of, IVF have increased since its inception 40 years ago, there is currently little state or federal regulation concerning the storage of embryos in embryo storage facilities .

f. In March of 2018, the failure of a storage tank at an Ohio fertility clinic caused the apparent loss of more than 4,000 frozen embryos and eggs, affecting 950 patients. Days after the storage tank failure in Ohio, a liquid nitrogen tank at an unrelated fertility clinic in California, containing thousands of eggs and embryos, malfunctioned, affecting another 400 patients.

g. It is in the best interest of the State to require that the Department of Health promulgate regulations governing the storage of human eggs, pre-embryos, and embryos in embryo storage facilities to guard against catastrophic storage system failure, such as those that occurred in California and Ohio, and the potential loss of such specimens that may result from long-term power outages during storms and other natural disasters.

C.26:2A-24 Definitions relative to embryo storage facilities.

2. As used in this act:

“Commissioner” means the Commissioner of Health.

“Department” means the Department of Health.

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

“Person” means any individual, corporation, company, association, organization, society, firm, partnership, joint stock company, or the State or any political subdivision thereof.

C.26:2A-25 Licensure for embryo storage facility.

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

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

C.26:2A-26 Rules, regulations.

4. a. The department shall promulgate rules and regulations pursuant to the “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-1 et seq.) governing the storage and care of human eggs, pre-embryos, and embryos by an embryo storage facility in accordance with:

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

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

(3) the U.S. Food and Drug Administration guidance on Current Good Tissue Practices.

b. The rules and regulations promulgated pursuant to this section shall promote safety and best practices among embryo storage facilities and, at a minimum: prescribe standards governing the operation, maintenance, and administration of embryo storage facilities; the safety and adequacy of the physical plant or the facilities; compliance with State and local fire safety codes; the number of staff and the qualifications of each staff member; the protection and safety of the equipment used by embryo storage facilities to process and store human eggs, pre-embryos, and embryos; the maintenance and confidentiality of records and furnishing of required information; the maintenance of all appropriate accreditations and certifications; the establishment of a quality management program; and the review of the scope of internal audits.

c. The department shall conduct an on-site facility inspection and shall evaluate the embryo storage facility to determine whether the facility complies with the provisions of this act.

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

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

f. If an embryo storage facility meets the requirements of this act and the rules and regulations promulgated hereunder, the department shall issue a license to the facility. A

license shall be valid for a period of one year and may be renewed at the end of that period, subject to continued compliance with the provisions of this act.

g. Nothing in this section shall be interpreted to permit the adoption of any code or standard which exceeds the standards established pursuant to the "State Uniform Construction Code Act," P.L.1975, c.217 (C.52:27D-119 et seq.).

C.26:2A-27 Application for licensure.

5. Any person operating an embryo storage facility on or after the effective date of this act or desiring to operate an embryo storage facility shall make application for licensure in a manner and on forms prescribed by the commissioner. The license application form shall include, but shall not be limited to, the following information:

- a. the name and address of the embryo storage facility
- b. a description of the facility's premises and facilities and the hours of its operation; and
- c. any other information the commissioner deems necessary to include on the license application form.

C.26:2A-28 Fees for licensure.

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

b. The income received from licensure and renewal fees pursuant to this section shall be appropriated to the department to effectuate the purposes of this act.

C.26:2A-29 Denial, suspension, revocation, refusal to renew license.

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

- a. Failure of an embryo storage facility or its operator to comply with the provisions of this act;
- b. Violation of the terms and conditions of a license by an embryo storage facility or its operator;
- c. Use of fraud or misrepresentation by an embryo storage facility or its operator in obtaining a license or in the subsequent operation of the facility;
- d. Refusal by an embryo storage facility or its operator to furnish the department with required files, reports, or records; or
- e. Refusal by an embryo storage facility or its operator to permit an inspection by an authorized representative of the department during normal operating hours.

C.26:2A-30 Notice, hearing.

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

b. The hearing shall take place within 60 days from the issuance or mailing of the notice and shall be conducted in accordance with the "Administrative Procedure Act," P.L. 1968, c.410 (C.52:14B-1 et seq.).

C.26:2A-31 Violations, third degree crime.

9. Any person who operates or assists in the operation of an embryo storage facility which does not have a license, who has used fraud or misrepresentation in obtaining a license or in the subsequent operation of a facility, who offers, advertises, or provides any service not authorized by a valid license, or who violates any other provision of this act, shall be guilty of a crime of the third degree.

10. This act shall take effect on the first day of the 14th month next following the date of enactment, but the Commissioner of Health may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of this act.

Approved December 4, 2019.