

[Second Reprint]

SENATE, No. 3075

STATE OF NEW JERSEY
218th LEGISLATURE

INTRODUCED OCTOBER 15, 2018

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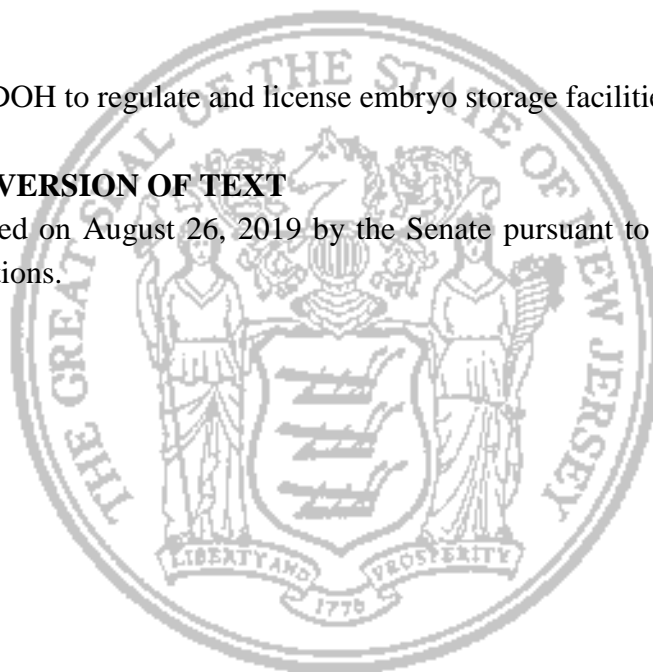
Assemblywomen Timberlake, Pinkin, Reynolds-Jackson and Mosquera

SYNOPSIS

Requires DOH to regulate and license embryo storage facilities.

CURRENT VERSION OF TEXT

As amended on August 26, 2019 by the Senate pursuant to the Governor's recommendations.



(Sponsorship Updated As Of: 5/24/2019)

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

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
7 1. The Legislature finds and declares that:

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

13 b. In 2016, the ¹federal¹ Centers for Disease Control and
14 Prevention reported that there were approximately 267,000 IVF
15 cycles performed in the United States, with more than five percent
16 of those cycles occurring in New Jersey. By the end of the century,
17 more than a million American patients who suffer from infertility
18 will undergo IVF procedures.

19 c. The use of ART in the United States is not as prevalent as its
20 use in other developed countries. In Japan, one in ¹**【twenty】** 20¹
21 children are born as a result of ART. In Norway the number is one
22 in ¹**【ten】** 10¹. As more women rise to executive positions in
23 America's board rooms, and IVF becomes a more financially viable
24 option because of increased health insurance coverage, ART will
25 provide more of an opportunity for couples to preserve their fertility
26 until they are ready to start a family.

27 d. IVF provides a pathway to motherhood for women who have
28 experienced life threatening diseases, such as cancer, and the
29 reproductive damage that is often a ¹**【consequences】** consequence¹
30 of the treatments associated with these illnesses.

31 e. While technological advances in, and success rates of, IVF
32 have increased since its inception 40 years ago, ¹**【regulations**
33 **surrounding】** there is currently little state or federal regulation
34 concerning¹ the storage of embryos in embryo storage facilities
35 ¹**【have not been addressed by legislatures across the country】**¹.

36 f. ¹In March of 2018, the failure of a storage tank at an Ohio
37 fertility clinic caused the apparent loss of more than 4,000 frozen
38 embryos and eggs, affecting 950 patients. Days after the storage
39 tank failure in Ohio, a liquid nitrogen tank at an unrelated fertility
40 clinic in California, containing thousands of eggs and embryos,
41 malfunctioned, affecting another 400 patients.

42 g.¹ It is in the best interest of the State to require that the

EXPLANATION – Matter enclosed in bold-faced brackets **【thus】** in the above bill is
not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹Senate SHH committee amendments adopted February 7, 2019.

²Senate amendments adopted in accordance with Governor's
recommendations August 26, 2019.

1 Department of Health promulgate regulations governing the storage
2 of human eggs, pre-embryos, and embryos in embryo storage
3 facilities to guard against catastrophic storage system failure, such
4 as ¹~~the~~¹ those that occurred in California and Ohio, and the
5 potential loss of such specimens that may result from long-term
6 power outages during storms and other natural disasters.

7
8 2. As used in this act:

9 “Commissioner” means the Commissioner of Health.

10 “Department” means the Department of Health.

11 “Embryo storage facility” means a facility which cryopreserves
12 and stores human eggs, pre-embryos, and embryos for later use in in
13 vitro fertilization, embryo transfer, gamete transfer, pronuclear
14 stage transfer and zygote transfer, and other procedures performed
15 to achieve a pregnancy or pregnancies. Embryo storage facility
16 shall also include the office of a licensed health care provider which
17 stores human eggs, ¹~~embryos,~~¹ pre-embryos, or embryos.

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

21
22 3. a. No person shall conduct, maintain, or operate an embryo
23 storage facility in this State unless licensed by the department
24 pursuant to the provisions of this act. A separate license shall be
25 ¹~~obtained~~¹ required for each ¹embryo storage facility¹ location.
26 The license shall be posted and displayed at all times in a prominent
27 location within the facility. No license issued pursuant to this act
28 shall be transferable. A change in the ownership of the facility shall
29 require notification to the department within 14 calendar days and
30 reapplication for licensure.

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

37
38 4. a. The department shall promulgate ¹rules and¹ regulations
39 ¹pursuant to the “Administrative Procedure Act,” P.L.1968, c.410
40 (C.52:14B-1 et seq.)¹ governing the storage and care of human
41 eggs, pre-embryos, and embryos by an embryo storage facility in
42 accordance with:

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

45 (2) standards for biorepositories established by the College of
46 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. ^{'[The rules and regulations promulgated pursuant to this act shall be adopted and amended in accordance with the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.).]'}

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.¹ Nothing in this ^{'[act] 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.).

5. ^{'[a.]'} Any person operating an embryo storage facility on or after the effective date of this act or desiring to operate an

1 embryo storage facility shall make application ¹for licensure¹ in
2 ¹~~the~~ a¹ manner and on ¹~~the~~¹ forms prescribed by the
3 commissioner. The license application form shall include, but shall
4 not be limited to, the following information:

5 ¹~~(1)~~ a.¹ the name and address of the embryo storage facility¹,
6 the operator of the facility, and the staff;

7 (2) the qualifications of the staff members, each member of the
8 board of directors of the corporation, and the embryo storage
9 facility operator;

10 ~~(3)~~ b.¹ a description of the facility's premises and facilities and
11 the hours of its operation¹; and

12 c. any other information the commissioner deems necessary to
13 include on the license application form¹.

14 ¹~~b.~~ If an embryo storage facility meets the requirements of this
15 act and of the rules and regulations promulgated hereunder, the
16 department shall issue a license to the facility. A license shall be
17 valid for a period of one year and may be renewed at the end of that
18 period, subject to continued compliance with the provisions of this
19 act.¹

20

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

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

27

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

30 a. Failure of an embryo storage facility or its operator to
31 comply with the provisions of this act;

32 b. Violation of the terms and conditions of a license by an
33 embryo storage facility or its operator;

34 c. Use of fraud or misrepresentation by an embryo storage
35 facility or its operator in obtaining a license or in the subsequent
36 operation of the facility;

37 d. Refusal by an embryo storage facility or its operator to
38 furnish the department with required files, reports, or records; or

39 e. Refusal by an embryo storage facility or its operator to
40 permit an inspection by an authorized representative of the
41 department during normal operating hours.

42

43 8. a. The department, before denying, suspending, revoking, or
44 refusing to renew a license, shall give notice to the operator
45 personally, or by certified or registered mail to the last known
46 address of the operator with return receipt requested. The notice
47 shall afford the operator with an opportunity to be heard in person

1 or by an attorney, and to offer evidence pertinent to the subject of
2 the hearing.

3 b. The hearing shall take place within 60 days from the
4 issuance or mailing of the notice and shall be conducted in
5 accordance with the "Administrative Procedure Act," P.L. 1968, c.
6 410 (C. 52:14B-1 et seq.).

7
8 9. Any person who operates or assists in the operation of an
9 embryo storage facility which does not have a license, who has used
10 fraud or misrepresentation in obtaining a license or in the
11 subsequent operation of a ¹**[center]** facility¹, who offers,
12 advertises, or provides any service not authorized by a valid license,
13 or who violates any other provision of this act ¹**[I]**,¹ shall be guilty
14 of a crime of the third degree.

15
16 10. This act shall take effect on the first day of the ²**[seventh]**
17 14th² month next following the date of enactment, but the
18 Commissioner of Health may take such anticipatory administrative
19 action in advance thereof as shall be necessary for the implementation
20 of this act.