

ASSEMBLY, No. 4605

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED OCTOBER 18, 2018

Sponsored by:

Assemblywoman PAMELA R. LAMPITT

District 6 (Burlington and Camden)

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District 33 (Hudson)

Assemblywoman VALERIE VAINIERI HUTTLE

District 37 (Bergen)

Co-Sponsored by:

Assemblywomen Timberlake and Pinkin

SYNOPSIS

Requires DOH to regulate and license embryo storage facilities.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 1/18/2019)

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 Centers for Disease Control and Prevention
14 reported that there were approximately 267,000 IVF cycles
15 performed in the United States, with more than five percent of those
16 cycles occurring in New Jersey. By the end of the century, more
17 than a million American patients who suffer from infertility will
18 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 twenty children
21 are born as a result of ART. In Norway the number is one in ten.
22 As more women rise to executive positions in America's board
23 rooms, and IVF becomes a more financially viable option because
24 of increased health insurance coverage, ART will provide more of
25 an opportunity for couples to preserve their fertility until they are
26 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 consequences of the treatments
30 associated with these illnesses.

31 e. While technological advances in, and success rates of, IVF
32 have increased since its inception 40 years ago, regulations
33 surrounding the storage of embryos in embryo storage facilities
34 have not been addressed by legislatures across the country.

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

42
43 2. As used in this act:

44 "Commissioner" means the Commissioner of Health.

45 "Department" means the Department of Health.

46 "Embryo storage facility" means a facility which cryopreserves
47 and stores human eggs, pre-embryos, and embryos for later use in in
48 vitro fertilization, embryo transfer, gamete transfer, pronuclear
49 stage transfer and zygote transfer, and other procedures performed

1 to achieve a pregnancy or pregnancies. Embryo storage facility
2 shall also include the office of a licensed health care provider which
3 stores human eggs, embryos, pre-embryos, or embryos.

4 "Person" means any individual, corporation, company,
5 association, organization, society, firm, partnership, joint stock
6 company, or the State or any political subdivision thereof.

7
8 3. a. No person shall conduct, maintain, or operate an embryo
9 storage facility in this State unless licensed by the department
10 pursuant to the provisions of this act. A separate license shall be
11 obtained for each location. The license shall be posted and
12 displayed at all times in a prominent location within the facility.
13 No license issued pursuant to this act shall be transferable. A
14 change in the ownership of the facility shall require notification to
15 the department within 14 calendar days and reapplication for
16 licensure.

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

23
24 4. a. The department shall promulgate regulations governing
25 the storage and care of human eggs, pre-embryos, and embryos by
26 an embryo storage facility in accordance with:

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

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

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

33 b. The regulations shall promote safety and best practices
34 among embryo storage facilities and, at a minimum, prescribe
35 standards governing the operation, maintenance, and administration
36 of embryo storage facilities, the safety and adequacy of the
37 physical plant or the facilities, compliance with State and local fire
38 safety codes, the number of staff and the qualifications of each staff
39 member, the protection and safety of the equipment used by embryo
40 storage facilities to process and store human eggs, pre-embryos, and
41 embryos, the maintenance and confidentiality of records and
42 furnishing of required information, the maintenance of all
43 appropriate accreditations and certifications, the establishment of a
44 quality management program, and the review of the scope of
45 internal audits. The rules and regulations promulgated pursuant to
46 this act shall be adopted and amended in accordance with the
47 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
48 seq.).

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

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

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

15 f. Nothing in this act shall be interpreted to permit the adoption
16 of any code or standard which exceeds the standards established
17 pursuant to the "State Uniform Construction Code Act," P.L.1975,
18 c.217 (C.52:27D-119 et seq.).
19

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

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

28 (2) the qualifications of the staff members, each member of the
29 board of directors of the corporation, and the embryo storage
30 facility operator;

31 (3) a description of the facility's premises and facilities and the
32 hours of its operation.

33 b. If an embryo storage facility meets the requirements of this
34 act and of the rules and regulations promulgated hereunder, the
35 department shall issue a license to the facility. A license shall be
36 valid for a period of one year and may be renewed at the end of that
37 period, subject to continued compliance with the provisions of this
38 act.
39

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

43 b. The income received from licensure and renewal fees
44 pursuant to this section shall be appropriated to the department to
45 effectuate the purposes of this act.
46

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

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

13

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

21 b. The hearing shall take place within 60 days from the
22 issuance or mailing of the notice and shall be conducted in
23 accordance with the "Administrative Procedure Act," P.L. 1968, c.
24 410 (C. 52:14B-1 et seq.).

25

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

33

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

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STATEMENT

42

43 This bill provides for the licensure of embryo storage facilities.
44 As used in the bill, "embryo storage facility" means a facility which
45 cryopreserves and stores human eggs, pre-embryos, and embryos
46 for later use in in vitro fertilization, embryo transfer, gamete
47 transfer, pronuclear stage transfer and zygote transfer, and other
48 medical procedures performed to achieve a pregnancy or
49 pregnancies, and includes the office of a licensed health care

1 provider which stores human eggs, embryos, pre-embryos, or
2 embryos.

3 Specifically, the bill stipulates that a person could not conduct,
4 maintain, or operate an embryo storage facility in this State unless
5 licensed by the Department of Health (DOH) pursuant to the
6 provisions of bill.

7 DOH would be required to promulgate regulations governing the
8 storage and care of human eggs, pre-embryos, and embryos by an
9 embryo storage facility in accordance with: Standards ISO 9001 and
10 ISO 20387 of the International Organization for Standardization;
11 standards for biorepositories established by the College of
12 American Pathologists Biorepository Accreditation Program; and
13 the U.S. Food and Drug Administration guidance on Current Good
14 Tissue Practices.

15 The regulations would promote safety and best practices among
16 embryo storage facilities and, at a minimum, prescribe standards
17 governing the operation, maintenance, and administration of
18 embryo storage facilities, the safety and adequacy of the physical
19 plant or the facilities, compliance with State and local fire safety
20 codes, the number of staff and the qualifications of each staff
21 member, the protection and safety of the equipment used by embryo
22 storage facilities to process and store human eggs, pre-embryos, and
23 embryos, the maintenance and confidentiality of records and
24 furnishing of required information, the maintenance of all
25 appropriate accreditations and certifications, the establishment of a
26 quality management program, and the review of the scope of
27 internal audits.

28 Under the provisions of the bill, the Commissioner of DOH
29 would establish a minimum licensing fee to be paid by each embryo
30 storage facility at the time of application and at every renewal of a
31 license, and the income received from licensure and renewal fees
32 would be used by DOH to effectuate the purposes of the bill.

33 DOH could deny, suspend, revoke, or refuse to renew a license
34 of an embryo storage facility for good cause, including, but not
35 limited to failure of the facility or its operator to comply with the
36 provisions of bill; violation of the terms and conditions of a license;
37 use of fraud or misrepresentation in obtaining a license or in the
38 subsequent operation of the facility; refusal to furnish DOH with
39 required files, reports, or records of the facility; or refusal to permit
40 an inspection of the facility by an authorized representative of DOH
41 during normal operating hours.

42 Before denying, suspending, revoking, or refusing to renew a
43 license, the bill would require DOH to give notice to the operator of
44 an embryo storage facility, personally, or by certified or registered
45 mail to the last known address of the operator with return receipt
46 requested. The notice would allow operator the opportunity to be
47 heard in person or by an attorney, and to offer evidence pertinent to
48 the subject of the hearing which would take place within 60 days
49 from the issuance or mailing of the notice.

1 The bill's provisions also specifies that any person who operates
2 or assists in the operation of an embryo storage facility which does
3 not have a license, or who has used fraud or misrepresentation in
4 obtaining a license or in the subsequent operation of the center, or
5 who offers, advertises, or provides any service not authorized by a
6 valid license, or who violates any other provision of this act would
7 be guilty of a crime of the third degree.