

[First Reprint]

**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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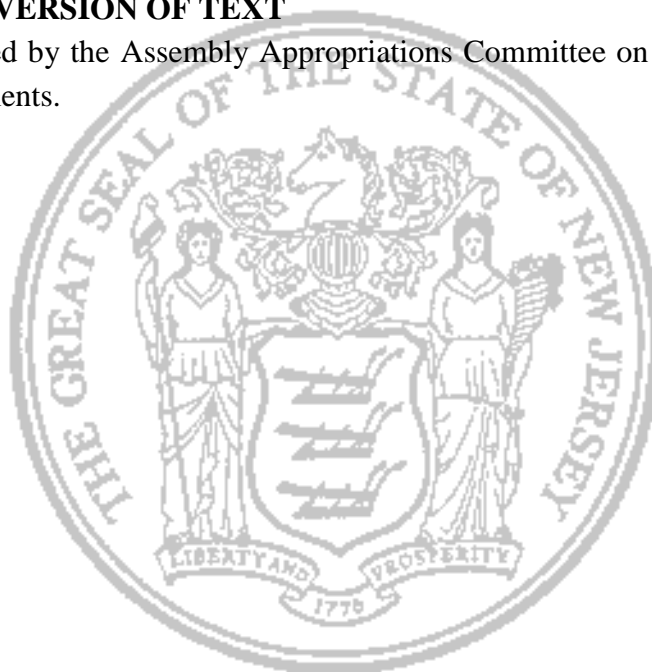
**Assemblywomen Timberlake, Pinkin, Reynolds-Jackson and Mosquera**

**SYNOPSIS**

Requires DOH to regulate and license embryo storage facilities.

**CURRENT VERSION OF TEXT**

As reported by the Assembly Appropriations Committee on May 20, 2019,  
with amendments.



**(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 <sup>1</sup>federal<sup>1</sup> 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 <sup>1</sup>**【twenty】** 20<sup>1</sup>  
21 children are born as a result of ART. In Norway the number is one  
22 in <sup>1</sup>**【ten】** 10<sup>1</sup>. 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 <sup>1</sup>**【consequences】** consequence<sup>1</sup>  
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, <sup>1</sup>**【regulations**  
33 **surrounding】** there is currently little state or federal regulation  
34 concerning<sup>1</sup> the storage of embryos in embryo storage facilities  
35 <sup>1</sup>**【have not been addressed by legislatures across the country】**<sup>1</sup>.

36 f. <sup>1</sup>In 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.<sup>1</sup> It is in the best interest of the State to require that the  
43 Department of Health promulgate regulations governing the storage  
44 of human eggs, pre-embryos, and embryos in embryo storage

**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:

<sup>1</sup>Assembly AAP committee amendments adopted May 20, 2019.

1 facilities to guard against catastrophic storage system failure, such  
2 as <sup>1</sup>the those that occurred in California and Ohio, and the  
3 potential loss of such specimens that may result from long-term  
4 power outages during storms and other natural disasters.

5  
6 2. As used in this act:

7 “Commissioner” means the Commissioner of Health.

8 “Department” means the Department of Health.

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

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

19  
20 3. a. No person shall conduct, maintain, or operate an embryo  
21 storage facility in this State unless licensed by the department  
22 pursuant to the provisions of this act. A separate license shall be  
23 <sup>1</sup>obtained required for each <sup>1</sup>embryo storage facility location.  
24 The license shall be posted and displayed at all times in a prominent  
25 location within the facility. No license issued pursuant to this act  
26 shall be transferable. A change in the ownership of the facility shall  
27 require notification to the department within 14 calendar days and  
28 reapplication for licensure.

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

35  
36 4. a. The department shall promulgate <sup>1</sup>rules and regulations  
37 <sup>1</sup>pursuant to the “Administrative Procedure Act,” P.L.1968, c.410  
38 (C.52:14B-1 et seq.)<sup>1</sup> governing the storage and care of human  
39 eggs, pre-embryos, and embryos by an embryo storage facility in  
40 accordance with:

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

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

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

47 b. The <sup>1</sup>rules and regulations <sup>1</sup>promulgated pursuant to this  
48 section<sup>1</sup> shall promote safety and best practices among embryo

1 storage facilities and, at a minimum<sup>1</sup> [.]<sup>1</sup> prescribe standards  
2 governing the operation, maintenance, and administration of  
3 embryo storage facilities<sup>1</sup> [.]<sup>1</sup> the safety and adequacy of the  
4 physical plant or the facilities<sup>1</sup> [.]<sup>1</sup> compliance with State and local  
5 fire safety codes<sup>1</sup> [.]<sup>1</sup> the number of staff and the qualifications of  
6 each staff member<sup>1</sup> [.]<sup>1</sup> the protection and safety of the equipment  
7 used by embryo storage facilities to process and store human eggs,  
8 pre-embryos, and embryos<sup>1</sup> [.]<sup>1</sup> the maintenance and  
9 confidentiality of records and furnishing of required  
10 information<sup>1</sup> [.]<sup>1</sup> the maintenance of all appropriate accreditations  
11 and certifications<sup>1</sup> [.]<sup>1</sup> the establishment of a quality management  
12 program<sup>1</sup> [.]<sup>1</sup> and the review of the scope of internal audits. <sup>1</sup> [The  
13 rules and regulations promulgated pursuant to this act shall be  
14 adopted and amended in accordance with the "Administrative  
15 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.).]<sup>1</sup>

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

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

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

30 f. <sup>1</sup>If an embryo storage facility meets the requirements of this  
31 act and the rules and regulations promulgated hereunder, the  
32 department shall issue a license to the facility. A license shall be  
33 valid for a period of one year and may be renewed at the end of that  
34 period, subject to continued compliance with the provisions of this  
35 act.

36 g.<sup>1</sup> Nothing in this <sup>1</sup> [act] section<sup>1</sup> shall be interpreted to permit  
37 the adoption of any code or standard which exceeds the standards  
38 established pursuant to the "State Uniform Construction Code Act,"  
39 P.L.1975, c.217 (C.52:27D-119 et seq.).

40

41 5. <sup>1</sup> [a.]<sup>1</sup> Any person operating an embryo storage facility on or  
42 after the effective date of this act or desiring to operate an embryo  
43 storage facility shall make application <sup>1</sup> for licensure<sup>1</sup> in <sup>1</sup> [the] a<sup>1</sup>  
44 manner and on <sup>1</sup> [the] <sup>1</sup> forms prescribed by the commissioner. The  
45 license application form shall include, but shall not be limited to,  
46 the following information:

47 <sup>1</sup> [(1)] a.<sup>1</sup> the name and address of the embryo storage facility<sup>1</sup> [.,  
48 the operator of the facility, and the staff;

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

4 (3) **】** b.<sup>1</sup> a description of the facility's premises and facilities and  
5 the hours of its operation<sup>1</sup>; and

6 c. any other information the commissioner deems necessary to  
7 include on the license application form<sup>1</sup>.

8 <sup>1</sup>**】** b. If an embryo storage facility meets the requirements of this  
9 act and of the rules and regulations promulgated hereunder, the  
10 department shall issue a license to the facility. A license shall be  
11 valid for a period of one year and may be renewed at the end of that  
12 period, subject to continued compliance with the provisions of this  
13 act. **】**<sup>1</sup>

14  
15 6. a. The commissioner shall establish a minimum fee to be  
16 paid by each embryo storage facility at the time of application for a  
17 license and at every renewal of a license.

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

21  
22 7. The department may deny, suspend, revoke, or refuse to  
23 renew a license for good cause, including, but not limited to:

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

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

28 c. Use of fraud or misrepresentation by an embryo storage  
29 facility or its operator in obtaining a license or in the subsequent  
30 operation of the facility;

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

33 e. Refusal by an embryo storage facility or its operator to  
34 permit an inspection by an authorized representative of the  
35 department during normal operating hours.

36  
37 8. a. The department, before denying, suspending, revoking, or  
38 refusing to renew a license, shall give notice to the operator  
39 personally, or by certified or registered mail to the last known  
40 address of the operator with return receipt requested. The notice  
41 shall afford the operator with an opportunity to be heard in person  
42 or by an attorney, and to offer evidence pertinent to the subject of  
43 the hearing.

44 b. The hearing shall take place within 60 days from the  
45 issuance or mailing of the notice and shall be conducted in  
46 accordance with the "Administrative Procedure Act," P.L. 1968, c.  
47 410 (C. 52:14B-1 et seq.).

1       9. Any person who operates or assists in the operation of an  
2 embryo storage facility which does not have a license, who has used  
3 fraud or misrepresentation in obtaining a license or in the  
4 subsequent operation of a <sup>1</sup>**center** facility<sup>1</sup>, who offers,  
5 advertises, or provides any service not authorized by a valid license,  
6 or who violates any other provision of this act <sup>1</sup>**[I]**<sub>1</sub><sup>1</sup> shall be guilty  
7 of a crime of the third degree.

8  
9       10. This act shall take effect on the first day of the seventh  
10 month next following the date of enactment, but the Commissioner  
11 of Health may take such anticipatory administrative action in  
12 advance thereof as shall be necessary for the implementation of this  
13 act.