

26:2A-23 to 26:2A-31
LEGISLATIVE HISTORY CHECKLIST
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LAWS OF: 2019 **CHAPTER:** 268

NJSA: 26:2A-23 to 26:2A-31 (Requires DOH to regulate and license embryo storage facilities)

BILL NO: S3075 (Substituted for A4605)

SPONSOR(S) Loretta Weinberg and others

DATE INTRODUCED: 10/15/2018

COMMITTEE: **ASSEMBLY:** AP

SENATE: Health, Human Services & Senior Citizens

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** 11/25/2019

SENATE: 8/26/2019

DATE OF APPROVAL: 12/4/2019

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (Second Reprint enacted) Yes

S3075

SPONSORS' STATEMENT: (Begins on page 5 of introduced bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY:** Yes

SENATE: Yes

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, *may possibly* be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

A4605

SPONSORS' STATEMENT: (Begins on page 5 of introduced bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY:** Yes Health & Senior

Services

Appropriations

SENATE: No

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, *may possibly* be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT:

No

LEGISLATIVE FISCAL ESTIMATE:

No

VETO MESSAGE:

Yes (Conditional)

GOVERNOR'S PRESS RELEASE ON SIGNING:

Yes

FOLLOWING WERE PRINTED:

To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext.103 or <mailto:refdesk@njstatelib.org>

REPORTS:

No

HEARINGS:

No

NEWSPAPER ARTICLES:

Yes

2019 "Bill to regulate embryo storage facilities signed into law," NJBIZ (New Brunswick, NJ) - December 5,

RWH/JA

P.L. 2019, CHAPTER 268, *approved December 4, 2019*
Senate, No. 3075 (*Second Reprint*)

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.

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

7 g.¹ It is in the best interest of the State to require that the
8 Department of Health promulgate regulations governing the storage
9 of human eggs, pre-embryos, and embryos in embryo storage
10 facilities to guard against catastrophic storage system failure, such
11 as ¹~~the~~¹ those that occurred in California and Ohio, and the
12 potential loss of such specimens that may result from long-term
13 power outages during storms and other natural disasters.

14
15 2. As used in this act:

16 “Commissioner” means the Commissioner of Health.

17 “Department” means the Department of Health.

18 “Embryo storage facility” means a facility which cryopreserves
19 and stores human eggs, pre-embryos, and embryos for later use in in
20 vitro fertilization, embryo transfer, gamete transfer, pronuclear
21 stage transfer and zygote transfer, and other procedures performed
22 to achieve a pregnancy or pregnancies. Embryo storage facility
23 shall also include the office of a licensed health care provider which
24 stores human eggs, ¹~~embryos,~~¹ pre-embryos, or embryos.

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

28
29 3. a. No person shall conduct, maintain, or operate an embryo
30 storage facility in this State unless licensed by the department
31 pursuant to the provisions of this act. A separate license shall be
32 ¹~~obtained~~ required¹ for each embryo storage facility¹ location.
33 The license shall be posted and displayed at all times in a prominent
34 location within the facility. No license issued pursuant to this act
35 shall be transferable. A change in the ownership of the facility shall
36 require notification to the department within 14 calendar days and
37 reapplication for licensure.

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

44
45 4. a. The department shall promulgate ¹rules and¹ regulations
46 ¹pursuant to the “Administrative Procedure Act,” P.L.1968, c.410
47 (C.52:14B-1 et seq.)¹ governing the storage and care of human

1 eggs, pre-embryos, and embryos by an embryo storage facility in
2 accordance with:

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

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

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

9 b. The rules and regulations promulgated pursuant to this
10 section shall promote safety and best practices among embryo
11 storage facilities and, at a minimum **[.];** prescribe standards
12 governing the operation, maintenance, and administration of
13 embryo storage facilities **[.];** the safety and adequacy of the
14 physical plant or the facilities **[.];** compliance with State and local
15 fire safety codes **[.];** the number of staff and the qualifications of
16 each staff member **[.];** the protection and safety of the equipment
17 used by embryo storage facilities to process and store human eggs,
18 pre-embryos, and embryos **[.];** the maintenance and
19 confidentiality of records and furnishing of required
20 information **[.];** the maintenance of all appropriate accreditations
21 and certifications **[.];** the establishment of a quality management
22 program **[.];** and the review of the scope of internal audits. **[The**
23 **rules and regulations promulgated pursuant to this act shall be**
24 **adopted and amended in accordance with the "Administrative**
25 **Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.).]**

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

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

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

40 f. If an embryo storage facility meets the requirements of this
41 act and the rules and regulations promulgated hereunder, the
42 department shall issue a license to the facility. A license shall be
43 valid for a period of one year and may be renewed at the end of that
44 period, subject to continued compliance with the provisions of this
45 act.

46 g. Nothing in this **[act]** section shall be interpreted to permit
47 the adoption of any code or standard which exceeds the standards

1 established pursuant to the "State Uniform Construction Code Act,"
2 P.L.1975, c.217 (C.52:27D-119 et seq.).

3

4 5. ¹~~1~~¹ Any person operating an embryo storage facility on
5 or after the effective date of this act or desiring to operate an
6 embryo storage facility shall make application ¹~~for licensure~~¹ in
7 ¹~~the~~ ¹~~a~~ manner and on ¹~~the~~ forms prescribed by the
8 commissioner. The license application form shall include, but shall
9 not be limited to, the following information:

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

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

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

17 c. any other information the commissioner deems necessary to
18 include on the license application form¹.

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

25

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

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

32

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

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

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

39 c. Use of fraud or misrepresentation by an embryo storage
40 facility or its operator in obtaining a license or in the subsequent
41 operation of the facility;

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

44 e. Refusal by an embryo storage facility or its operator to
45 permit an inspection by an authorized representative of the
46 department during normal operating hours.

SENATE, No. 3075

STATE OF NEW JERSEY 218th LEGISLATURE

INTRODUCED OCTOBER 15, 2018

Sponsored by:

Senator LORETTA WEINBERG

District 37 (Bergen)

Senator M. TERESA RUIZ

District 29 (Essex)

SYNOPSIS

Requires DOH to regulate and license embryo storage facilities.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 10/30/2018)

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

1 stage transfer and zygote transfer, and other procedures performed
2 to achieve a pregnancy or pregnancies. Embryo storage facility
3 shall also include the office of a licensed health care provider which
4 stores human eggs, embryos, pre-embryos, or embryos.

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

8

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

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

24

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

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

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

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

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

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- 1 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
2 seq.).
- 3 c. The department shall conduct an on-site facility inspection
4 and shall evaluate the embryo storage facility to determine whether
5 the facility complies with the provisions of this act.
- 6 d. The department shall have the authority to inspect and
7 examine the physical plant or facilities of an embryo storage facility
8 and to inspect all documents, records, files, or other data maintained
9 pursuant to this act during normal operating hours and without prior
10 notice.
- 11 e. The department shall request the appropriate State and local
12 fire, health, and building officials to conduct examinations and
13 inspections to determine compliance with State and local
14 ordinances, codes, and regulations by an embryo storage facility.
15 The inspections shall be conducted and the results reported to the
16 department within 60 days after the request.
- 17 f. Nothing in this act shall be interpreted to permit the adoption
18 of any code or standard which exceeds the standards established
19 pursuant to the "State Uniform Construction Code Act," P.L.1975,
20 c.217 (C.52:27D-119 et seq.).
- 21
- 22 5. a. Any person operating an embryo storage facility on or
23 after the effective date of this act or desiring to operate an embryo
24 storage facility shall make application in the manner and on the
25 forms prescribed by the commissioner. The license application
26 form shall include, but shall not be limited to, the following
27 information:
- 28 (1) the name and address of the embryo storage facility, the
29 operator of the facility, and the staff;
- 30 (2) the qualifications of the staff members, each member of the
31 board of directors of the corporation, and the embryo storage
32 facility operator;
- 33 (3) a description of the facility's premises and facilities and the
34 hours of its operation.
- 35 b. If an embryo storage facility meets the requirements of this
36 act and of the rules and regulations promulgated hereunder, the
37 department shall issue a license to the facility. A license shall be
38 valid for a period of one year and may be renewed at the end of that
39 period, subject to continued compliance with the provisions of this
40 act.
- 41
- 42 6. a. The commissioner shall establish a minimum fee to be
43 paid by each embryo storage facility at the time of application for a
44 license and at every renewal of a license.
- 45 b. The income received from licensure and renewal fees
46 pursuant to this section shall be appropriated to the department to
47 effectuate the purposes of this act.

- 1 7. The department may deny, suspend, revoke, or refuse to
2 renew a license for good cause, including, but not limited to:
3 a. Failure of an embryo storage facility or its operator to
4 comply with the provisions of this act;
5 b. Violation of the terms and conditions of a license by an
6 embryo storage facility or its operator;
7 c. Use of fraud or misrepresentation by an embryo storage
8 facility or its operator in obtaining a license or in the subsequent
9 operation of the facility;
10 d. Refusal by an embryo storage facility or its operator to
11 furnish the department with required files, reports, or records; or
12 e. Refusal by an embryo storage facility or its operator to
13 permit an inspection by an authorized representative of the
14 department during normal operating hours.

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

23 b. The hearing shall take place within 60 days from the
24 issuance or mailing of the notice and shall be conducted in
25 accordance with the "Administrative Procedure Act," P.L. 1968, c.
26 410 (C. 52:14B-1 et seq.).

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

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

41

42

43

STATEMENT

44

45 This bill provides for the licensure of embryo storage facilities.
46 As used in the bill, "embryo storage facility" means a facility which
47 cryopreserves and stores human eggs, pre-embryos, and embryos
48 for later use in in vitro fertilization, embryo transfer, gamete

1 transfer, pronuclear stage transfer and zygote transfer, and other
2 medical procedures performed to achieve a pregnancy or
3 pregnancies, and includes the office of a licensed health care
4 provider which stores human eggs, embryos, pre-embryos, or
5 embryos.

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

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

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

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

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

45 Before denying, suspending, revoking, or refusing to renew a
46 license, the bill would require DOH to give notice to the operator of
47 an embryo storage facility, personally, or by certified or registered
48 mail to the last known address of the operator with return receipt

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7

1 requested. The notice would allow operator the opportunity to be
2 heard in person or by an attorney, and to offer evidence pertinent to
3 the subject of the hearing which would take place within 60 days
4 from the issuance or mailing of the notice.

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

ASSEMBLY APPROPRIATIONS COMMITTEE

STATEMENT TO

[First Reprint]

SENATE, No. 3075

STATE OF NEW JERSEY

DATED: MAY 20, 2019

The Assembly Appropriations Committee reports favorably Senate Bill No. 3075 (1R).

Senate Bill No. 3075 (1R) provides for the licensure of embryo storage facilities. As used in the bill, “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 medical procedures performed to achieve a pregnancy or pregnancies, and includes the office of a licensed health care provider which stores human eggs, pre-embryos, or embryos.

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

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

The regulations would 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.

If an embryo storage facility meets the requirements and the rules and regulations promulgated under the bill, DOH would issue a license to the facility which would 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 the bill.

The bill would require that any person operating or desiring to operate an embryo storage facility on or after the effective date of the bill to apply for licensure in a manner and on forms prescribed by the Commissioner of DOH. As amended, the provisions of the bill stipulate that the license application form would include, but not be limited to, information concerning: the name and address of the embryo storage facility; a description of the storage facility's premises and hours of operation; and any other information the commissioner deems necessary.

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

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

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

The bill's provisions also specifies that any person who operates or assists in the operation of an embryo storage facility which does not have a license, or who has used fraud or misrepresentation in obtaining a license or in the subsequent operation of the facility, or who offers, advertises, or provides any service not authorized by a valid license, or who violates any other provision of this act would be guilty of a crime of the third degree, which is punishable by imprisonment for three to five years, a fine of up to \$15,000, or both.

As reported, this bill is identical to Assembly Bill No. 4605, as amended and reported by the committee on this date.

FISCAL IMPACT:

This bill is not certified as requiring a fiscal note.

SENATE HEALTH, HUMAN SERVICES AND SENIOR
CITIZENS COMMITTEE

STATEMENT TO
SENATE, No. 3075

with committee amendments

STATE OF NEW JERSEY

DATED: FEBRUARY 7, 2019

The Senate Health, Human Services and Senior Citizens Committee reports favorably and with committee amendments Senate Bill No. 3075.

As amended by the committee, this bill provides for the licensure of embryo storage facilities. As used in the bill, “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 medical procedures performed to achieve a pregnancy or pregnancies, and includes the office of a licensed health care provider which stores human eggs, pre-embryos, or embryos.

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

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

The regulations would 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.

If an embryo storage facility meets the requirements and the rules and regulations promulgated under the bill, DOH would issue a license to the facility which would 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 the bill.

The bill would require that any person operating or desiring to operate an embryo storage facility on or after the effective date of the bill to apply for licensure in a manner and on forms prescribed by the Commissioner of DOH. As amended, the provisions of the bill stipulate that the license application form would include, but not be limited to, information concerning: the name and address of the embryo storage facility; a description of the storage facility's premises and hours of operation; and any other information the commissioner deems necessary.

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

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

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

The bill's provisions also specifies that any person who operates or assists in the operation of an embryo storage facility which does not have a license, or who has used fraud or misrepresentation in obtaining a license or in the subsequent operation of the facility, or who offers, advertises, or provides any service not authorized by a valid license, or who violates any other provision of this act would be guilty of a crime of the third degree, which is punishable by imprisonment for three to five years, a fine of up to \$15,000, or both.

COMMITTEE AMENDMENTS

The committee amended the bill to remove the requirement that the license application form contain information about: the name and

addresses of the operator of the embryo storage facility and the staff; and the qualifications of the staff members, every member of the board of directors of the corporation, and of the operator of the facility. The amendments stipulate that the license application form would also include other information the Commissioner of DOH deemed necessary.

The committee also amended the bill to make technical, punctuation, and grammatical corrections.

ASSEMBLY, No. 4605

STATE OF NEW JERSEY 218th LEGISLATURE

INTRODUCED OCTOBER 18, 2018

Sponsored by:

Assemblywoman PAMELA R. LAMPITT

District 6 (Burlington and Camden)

Assemblyman RAJ MUKHERJI

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.

39

40

41

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.

A4605 LAMPITT, MUKHERJI

7

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.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY, No. 4605

STATE OF NEW JERSEY

DATED: JANUARY 17, 2019

The Assembly Health and Senior Services Committee reports favorably Assembly Bill No. 4605.

This bill provides for the licensure of embryo storage facilities. As used in the bill, “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 medical procedures performed to achieve a pregnancy or pregnancies, and includes the office of a licensed health care provider which stores human eggs, embryos, pre-embryos, or embryos.

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

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

The regulations would 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.

Under the provisions of the bill, the Commissioner of DOH would establish a minimum licensing fee to be paid by each embryo

storage facility at the time of application and at every renewal of a license, and the income received from licensure and renewal fees would be used by DOH to effectuate the purposes of the bill.

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

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

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

ASSEMBLY APPROPRIATIONS COMMITTEE

STATEMENT TO

ASSEMBLY, No. 4605

with committee amendments

STATE OF NEW JERSEY

DATED: MAY 20, 2019

The Assembly Appropriations Committee reports favorably and with committee amendments Assembly Bill No. 4605.

As amended by the committee, this bill provides for the licensure of embryo storage facilities. As used in the bill, “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 medical procedures performed to achieve a pregnancy or pregnancies, and includes the office of a licensed health care provider which stores human eggs, pre-embryos, or embryos.

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

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

The regulations would 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.

If an embryo storage facility meets the requirements and the rules and regulations promulgated under the bill, DOH would issue a license

to the facility which would 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 the bill.

The bill would require that any person operating or desiring to operate an embryo storage facility on or after the effective date of the bill to apply for licensure in a manner and on forms prescribed by the Commissioner of DOH. As amended, the provisions of the bill stipulate that the license application form would include, but not be limited to, information concerning: the name and address of the embryo storage facility; a description of the storage facility's premises and hours of operation; and any other information the commissioner deems necessary.

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

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

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

The bill's provisions also specifies that any person who operates or assists in the operation of an embryo storage facility which does not have a license, or who has used fraud or misrepresentation in obtaining a license or in the subsequent operation of the facility, or who offers, advertises, or provides any service not authorized by a valid license, or who violates any other provision of this act would be guilty of a crime of the third degree, which is punishable by imprisonment for three to five years, a fine of up to \$15,000, or both.

As amended by the committee, Assembly Bill No. 4605 is identical to Senate Bill No. 3075 (1R), also reported by the committee on this date.

COMMITTEE AMENDMENTS

The committee amended the bill to remove the requirement that the license application form contain information about: the name and addresses of the operator of the embryo storage facility and the staff; and the qualifications of the staff members, every member of the board of directors of the corporation, and of the operator of the facility. The amendments stipulate that the license application form would also include other information the Commissioner of DOH deemed necessary.

The committee also amended the bill to make technical, punctuation, and grammatical corrections.

FISCAL IMPACT:

This bill is not certified as requiring a fiscal note.

SENATE BILL NO. 3075
(First Reprint)

To the Senate:

Pursuant to Article V, Section I, Paragraph 14 of the New Jersey Constitution, I am returning Senate Bill No. 3075 (First Reprint) with my recommendations for reconsideration.

This bill requires the New Jersey Department of Health (the "Department") to license embryo storage facilities and proffer regulations that reflect best practices for safe storage of human eggs and embryos. Nineteen clinics within the State, housing approximately 100,000 frozen specimens, currently specialize in reproductive endocrinology and in-vitro fertilization. For thousands of New Jerseyans, these facilities secure the option to build a family, often following expensive, invasive, and time-consuming treatments. These services are a source of hope for women with cancer diagnoses who should not have to decide whether to prioritize their health over their desire for a family. They assist members of the LGBTQT community, help couples struggling to conceive, and give others control over their family planning options. Consumers place their trust in these facilities, and it is critical that the centers deliver.

Recent equipment malfunctions at clinics in Ohio and California resulted in the destruction of thousands of egg and embryo specimens, devastating the individuals who staked their futures on those stored embryos and exposing a lack of oversight over fertility centers across the nation. There are currently no regulatory or legislative safeguards in place to prevent a similar incident occurring in New Jersey and no professional association or federal or state agency monitors these facilities with the close attention that should be required for entities entrusted with an individual's genetic material.

I commend the bill's sponsors for recognizing the need for rigorous oversight of these facilities, their equipment and processes. This regulatory program, however, will be the first of its kind in the nation and will require specialized expertise and careful consideration. The Department must examine the practices of the patchwork of entities, including the Food and Drug Administration, the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, and the College of American Pathologists, that presently have some degree of control over these storage facilities.

The Department of Health will also need to approach licensure of human tissue storage facilities, milk banks and other related facilities holistically, as each of these entities are currently unregulated but are gaining popularity across the county. New Jersey is positioned to be a leader in this area, but we must not sacrifice the quality of this important licensing program by rushing through the regulatory process. Accordingly, I have recommended an extension of the effective date of the bill to allow additional time for the Department to thoughtfully implement the requirements outlined in the legislation.

Therefore, I herewith return Senate Bill No. 3075 (First Reprint) and recommend that it be amended as follows:

Page 6, Section 10, Line 14: Delete "seventh" and insert "fourteenth"

Respectfully,

[seal]

/s/ Philip D. Murphy
Governor

Attest:

/s/ Matthew J. Platkin

Chief Counsel to the Governor

Governor Murphy Takes Action on Legislation

08/23/2019

Governor Murphy Takes Action on Legislation

TRENTON – Today, Governor Phil Murphy signed the following bills and resolutions into law:

A3118 (Burzichelli, Schepisi, Jasey/Bucco, Thompson) - Establishes licensure for master hearth specialists.

A4420 (Holley/Scutari) - Modifies certain fees charged by check casher licensees.

A4482 (Verrelli, Murphy, Downey/Greenstein) - Establishes "Task Force on the Prevention of Sexual Violence Against Persons with Developmental Disabilities" in DHS.

A5293 (Pinkin, Zwicker, Lopez, McKeon/Smith, Bateman, Greenstein) - Makes various changes to laws governing remediation of contaminated sites.

A5390 (Tucker, Mukherji, Timberlake/Gopal, Oroho) - Provides in-State tuition at public institutions of higher education to individuals living in NJ who are entitled to educational assistance under US Department of Veterans Affairs' Vocational Rehabilitations and Employment Program.

S499 (Vitale, Madden/Downey, Houghtaling, Zwicker) - Provides for improved system for eligibility determination for Medicaid and NJ FamilyCare.

[Copy of Statement on S499](#)

S785 (Sarlo, Lagana/Calabrese, Mukherji) - Requires Police Training Commission to develop supplemental training course for certain county corrections officers.

S1014 (Rice/Wimberly, Mukherji) - Changes composition of State Employment and Training Commission.

S1126 (Bucco, Doherty, Bucco/Coughlin, Webber) - Requires public school districts to provide instruction on "New Jersey Safe Haven Infant Protection Act" as part of New Jersey Student Learning Standards.

S1403 (Diegnan, Singleton/DeAngelo, Mazzeo, Sumter) - Permits service credit transferred from another State-administered retirement system to apply toward creditable service requirement for retirement in SPRS.

S1887 (Singleton, Greenstein/DeAngelo, Wirths, Space) - Directs Commissioner of Labor and Workforce Development to establish pilot program to assist certain unemployed and underemployed individuals to complete industry-valued Credentials in 12 months.

S1948 (Vitale/Quijano, Holley, Lopez) - Makes Supplemental Nutrition Assistance Program Employment and Training Provider Demonstration Project permanent and renames program.

S2507 (Singleton, Pou/Danielsen, DeCroce) - Prohibits sale or lease of access to certain dental provider network contracts.

S2538 (Singleton, Pennacchio/Kean, Murphy, DeCroce, Armato) - Makes New Jersey National Guard members with NGB-22 form eligible for certain veterans' benefits.

S2660 (Gopal, Sarlo/Downey, Houghtaling, Schaer) - Establishes grant program and tuition reimbursement program for certain teachers of science, technology, engineering, and mathematics; appropriates \$5 million to DOE.

[Copy of Statement on S2660](#)

S2690 (Ruiz, Cryan, Beach, Turner, Andrzejczak/McKeon, Dancer, Land) - Prohibits pharmacy benefits managers and carriers from engaging in "clawback" and "gag clause" practices; requires certain disclosures by pharmacists; requires Director of Division of Consumer Affairs to conduct public information campaign.

S2691 (Kean, Cunningham/Quijano, Vainieri Huttle, Reynolds-Jackson) - Makes supplemental appropriation of \$100,000 to Commission on Human Trafficking.

[Copy of Statement on S2691](#)

S3100 (Weinberg, Addiego/Benson, Vainieri Huttle, Mukherji) - Revises definition of hemophilia and expands hemophilia treatment program.

SJR73 (Singleton/Murphy, Verrelli, Dancer) - Urges U.S. Congress to pass "Military Hunger Prevention Act."

Governor Murphy conditionally vetoed the following bills:

A3717 (Mukherji, Downey, Houghtaling/Greenstein, Gopal) - Prohibits pharmacy benefits managers from making certain retroactive reductions in claims payments to pharmacies; requires pharmacy benefits managers to disclose certain product information to pharmacies.

[Copy of Statement on A3717](#)

A5363 (Burzichelli, Benson, Murphy/Gopal) - Requires carriers that offer health benefits plans to provide new or existing subscribers with notification of certain hospital and health system contract expirations.

[Copy of Statement on A5363](#)

S834 (Scutari, Greenstein/Jones, Pintor Marin) - Prohibits resale of non-prescription diabetes test devices by pharmacists.

[Copy of Statement on S834](#)

S2804 (Ruiz, Turner/Lopez, McKnight, Verrelli) - Requires young children entering public schools or Head Start Programs for first time to have comprehensive eye examination completed.

[Copy of Statement on S2804](#)

S3075 (Weinberg, Ruiz/Lampitt, Mukherji, Vainieri Huttle) - Requires DOH to regulate and license embryo storage facilities.

[Copy of Statement on S3075](#)

S3309 (Vitale, Greenstein/Greenwald, Pintor Marin, Reynolds-Jackson) - Establishes New Jersey Violence Intervention Program to fund violence reduction initiatives.

[Copy of Statement on S3309](#)

S3330 (Addiego, Singleton/Jones, Vainieri Huttle, Lampitt, Murphy) - Establishes pilot program in DCF to study impact of child care services provided by community providers operating in public school facilities; requires community providers to meet certain criteria.

[Copy of Statement on S3330](#)

S3661 (Singleton, Oroho/Jasey, Wirths, Webber) - Clarifies assessment payment and election participation requirements in planned real estate developments.

[Copy of Statement on S3661](#)

Governor Murphy absolute vetoed the following bills and resolutions:

A4135 (Land, Taliaferro/Sweeney, Andrzejczak) - Concerns use of digital parking meters to monitor parking compliance; establishes fund to encourage designated drivers.

[Copy of Statement on A4135](#)

AJR158 (Houghtaling, Downey, Mosquera/Gopal) - Establishes New Jersey Task Force on Medicaid Financial

Resource Limits.

[Copy of Statement on AJR158](#)

S1364 (Andrzejczak/Land, Milam) - Provides funding from the General Fund to the Greater Wildwoods Tourism Improvement and Development Authority; appropriates \$4 million.

[Copy of Statement on S1364](#)