

ASSEMBLY, No. 664

STATE OF NEW JERSEY

219th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2020 SESSION

Sponsored by:

Assemblywoman VALERIE VAINIERI HUTTLE

District 37 (Bergen)

SYNOPSIS

“Reproductive Donation Safety Act.”

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.



1 **AN ACT** concerning the regulation of semen banks and
2 supplementing Title 26 of the Revised Statutes and Title 2C of
3 the New Jersey Statutes.

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

7
8 1. This act shall be known and may be cited as the
9 “Reproductive Donation Safety Act.”

10
11 2. As used in this act:

12 “Assisted reproductive technology” means clinical treatments
13 and laboratory procedures that are performed with the intent of
14 establishing a pregnancy.

15 “Collection” means the obtaining of semen from donors.

16 “Commissioner” means the Commissioner of Health.

17 “Department” means the Department of Health.

18 “Distribution” means the removal of semen from a semen bank
19 to any other location for processing or storage or for the purpose of
20 providing the semen for reproductive or research purposes.

21 “Donor” means an individual who donates semen from that
22 individual to a semen bank for use in assisted reproductive
23 technology procedures.

24 “Federal regulations” means regulations adopted by the federal
25 Food and Drug Administration as set forth at 21 CFR Part 1271
26 governing human reproductive tissue banks and any other federal
27 regulations that may apply to the operation of semen banks.

28 “Licensee” means a person holding a license under the
29 provisions of this act.

30 “Person” means a natural person or a partnership, association,
31 corporation, institution, agency, or other similar type of entity.

32 “Processing” means the technical stages required to prepare and
33 identify semen as to its suitability.

34 “Registry” means the New Jersey Semen Donor Registry
35 established pursuant to section 6 of this act.

36 “Semen bank” means a commercial or noncommercial activity
37 involving the handling of human semen that participates in the
38 collection, processing, storage, or distribution of semen for use in
39 assisted reproductive technology procedures.

40 “Storage” means the holding of semen in connection with
41 collection or processing prior to distribution.

42
43 3. a. A person shall not operate or conduct a semen bank in
44 this State unless licensed by the commissioner under the provisions
45 of this act. The license required by this act shall be in addition to
46 any other license or permit required by a local board of health or
47 other body exercising the powers of such a board in a municipality
48 in this State.

1 b. The commissioner shall not license a person to operate or
2 conduct a semen bank pursuant to this act unless the commissioner
3 is satisfied that the applicant for licensure has demonstrated good
4 character, competency, and integrity, and the applicant shall furnish
5 such information to the commissioner as the commissioner may
6 require for this purpose.

7 c. A license issued pursuant to this section shall expire on
8 December 31 of each calendar year, and application for renewal
9 therefor shall be made on or before November 10 on forms provided
10 by the department. A fee necessary to conduct semen bank
11 licensure operations, as provided in subsection d. of this section,
12 shall accompany the original application for a license and each
13 renewal thereof. The licensee shall conspicuously display the
14 original or a certified copy of the license at the premises occupied
15 as a semen bank.

16 d. (1) The commissioner shall charge a fee for each license or
17 renewal thereof in an amount determined by the commissioner to be
18 reasonably necessary to cover the cost to the department of carrying
19 out the provisions of this act, but the fee may vary based on the
20 number of collections made by a facility.

21 (2) The commissioner may, pursuant to the "Administrative
22 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), periodically
23 increase the fees to reflect increased State costs in semen bank
24 licensure operations.

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

28 f. A license shall be issued to any person who has been
29 conducting a semen bank prior to the effective date of this act upon
30 submission of a properly completed application on a form and in a
31 manner prescribed by the commissioner, including documentation
32 to the satisfaction of the commissioner that the semen bank is
33 accredited by the American Association of Tissue Banks and is in
34 compliance with federal regulations, and payment of the application
35 fee. The license shall be renewable as provided in this act and shall
36 be subject to all the provisions of this act.

37 g. (1) A license issued in accordance with the provisions of
38 this act may be suspended or revoked by the commissioner for a
39 violation of any of the provisions of this act or any rules or
40 regulations adopted pursuant thereto.

41 (2) (a) The commissioner, before refusing to grant a license, or
42 before suspending or revoking a license previously granted, except
43 as hereinafter provided in this act, shall give notice to the applicant
44 or licensee personally, or by mail addressed to that person at the
45 person's last known address, and shall afford that person an
46 opportunity to be heard with respect thereto at a time and place
47 specified in the notice. The applicant or licensee shall have the

1 right to be heard in person or by an attorney, and to offer evidence
2 pertinent to the subject of the hearing.

3 (b) A duly certified copy of the order of the commissioner
4 issued as a result of the hearing shall be served on the applicant or
5 the licensee personally, or by mail addressed to that person at the
6 person's last known address.

7 (c) If the applicant or licensee is a corporation, the notice issued
8 pursuant to subparagraph (a), and the order issued pursuant to
9 subparagraph (b), of this paragraph shall be served in the same
10 manner upon an officer or registered agent of the corporation.

11

12 4. a. A licensee shall not collect semen without having first
13 obtained the following from the prospective donor, on a form and in
14 a manner prescribed by the commissioner:

15 (1) a completed registration statement which shall set forth the
16 name and address of the donor and shall contain such other
17 information as prescribed by regulation of the commissioner or
18 required pursuant to federal regulations; and

19 (2) a donor information sharing statement as set forth in section
20 5 of this act.

21 b. (1) The commissioner shall establish by regulation
22 standards of operation for semen banks, including standards for the
23 collection, processing, storage, and distribution of semen, in
24 consultation with the American Association of Tissue Banks and
25 the American Society for Reproductive Medicine, and may
26 incorporate in the regulations by reference the requirements or
27 guidelines adopted by those entities, as well as federal regulations.

28 (2) The regulations shall include, but not be limited to,
29 provision for:

30 (a) qualifications for personnel employed in a semen bank;

31 (b) restrictions upon the use of semen donors;

32 (c) standards for collection, processing, storage, and distribution
33 of semen; and

34 (d) evaluation of the performance of semen banks.

35 c. (1) The commissioner shall impose a limit on semen
36 donations by an individual donor in accordance with the
37 recommendations of the American Society for Reproductive
38 Medicine.

39 (2) A semen bank shall report the information contained in the
40 completed registration statement that it obtains for each donor to the
41 New Jersey Semen Donor Registry established pursuant to section 6
42 of this act, and shall check with the registry prior to obtaining each
43 donation of semen from any donor, as prescribed by regulation of
44 the commissioner for the purposes of paragraph (1) of this
45 subsection.

46

47 5. a. (1) The donor information sharing statement, required
48 pursuant to section 4 of this act, shall specify the level of

1 information that shall be shared with an individual 18 years of age
2 or older if that individual submits a written, notarized request to
3 obtain information pursuant to subsection d. of this section.

4 (2) The donor may, in the future, ask to update and submit a
5 revised statement to the semen bank, which shall report this
6 information to the New Jersey Semen Donor Registry.

7 b. The donor information sharing statement shall specify the
8 following options, from which the donor may select one:

9 (1) "Complete information sharing" means a donor consents to
10 the release of the donor's name, last known address, and telephone
11 number, if available;

12 (2) "Intermediary information sharing only" means a donor does
13 not consent to the release of the information set forth in paragraph
14 (1) of this subsection, but agrees to communication with the
15 individual requesting the information through a third party
16 designated by the donor on the original or revised statement;

17 (3) "Medical information sharing only" means a donor does not
18 consent to the release of the information set forth in paragraph (1)
19 of this subsection, but agrees to periodic communication limited to
20 the sharing of non-identifying family medical history information,
21 with the individual requesting the information through a third party
22 designated by the donor on the original or revised statement.

23 c. The licensee shall maintain a copy of the completed and any
24 revised donor information sharing statement.

25 d. (1) An individual who is 18 years of age or older may submit
26 to the registry a written, notarized request for information about the
27 person whom the individual has reason to believe was a donor.

28 (2) If the donor submitted a donor information sharing statement
29 specifying "complete information sharing," the registry shall
30 provide that donor information to the requester.

31 (3) If the donor submitted a donor information sharing statement
32 specifying "intermediary information sharing only," the registry
33 shall inform the requester of the donor's wish to communicate with
34 the requester through the third party designated by the donor on the
35 donor information sharing statement.

36 (4) If the donor submitted a donor information sharing statement
37 specifying "medical information sharing only," the registry shall
38 inform the requester of the donor's wish for periodic
39 communication limited to the sharing of non-identifying family
40 medical history information with the requester through a third party
41 designated by the donor on the donor information sharing statement.

42 (5) If the donor submits a revised statement to the semen bank
43 that is reported to the registry pursuant to paragraph (2) of
44 subsection a. of this section, the registry shall share information
45 with the requester based on the revised statement in accordance
46 with the provisions of this section.

1 6. a. The commissioner shall establish and operate a Statewide
2 registry, to be designated as the New Jersey Semen Donor Registry,
3 which shall be the repository for information obtained from semen
4 banks pursuant to sections 4 and 5 of this act.

5 b. The commissioner shall adopt regulations for the
6 implementation, operation, and evaluation of the registry, including,
7 but not limited to, regulations that prescribe the manner for a semen
8 bank to submit information to, and for a semen bank or an
9 individual to obtain information from, the registry, and establish
10 procedures to ensure the accuracy and confidentiality of
11 information submitted to the registry.

12 c. The commissioner may contract with a public or private
13 entity to implement or operate the registry.

14 d. All information collected or developed by the registry that
15 identifies or could be used to identify a person shall be considered
16 confidential information, subject to the provisions of section 5 of
17 this act, and shall be treated as such by a semen bank, and shall not
18 be subject to civil or administrative subpoena or discovery in a civil
19 action, including, but not limited to, a judicial, administrative,
20 arbitration, or mediation proceeding.

21 e. A person who reports information to the registry or acts on
22 information obtained from the registry in good faith, or otherwise
23 takes any action, in accordance with the provisions of this act and
24 the rules and regulations adopted pursuant thereto, shall be immune
25 from any civil or criminal liability that might otherwise be incurred
26 or imposed with respect to those actions.

27

28 7. a. The commissioner shall be authorized to enter and inspect
29 any semen bank and to make such investigation of the premises and
30 the books and records as is reasonably necessary to carry out the
31 provisions of this act.

32 b. It shall be a violation of this act for any person to obstruct,
33 hinder, delay, or interfere, by force or otherwise, with the
34 performance by the commissioner of any duty under the provisions
35 of this act.

36 c. If the commissioner has reason to believe that a condition
37 exists or has occurred at a semen bank, in violation of the
38 provisions of this act, which is dangerous to the public health, the
39 commissioner may order that semen bank to correct the violation
40 and may suspend the license of the semen bank until the correction
41 is completed. If a licensee denies that a violation exists or has
42 occurred, the licensee shall have the right to apply to the
43 commissioner for a hearing, in which case the hearing shall be held
44 and a decision rendered within 72 hours of the receipt of the
45 licensee's request. If the commissioner rules against the licensee,
46 the licensee shall have the right to apply to the Superior Court for
47 injunctive relief against the commissioner's order.

1 d. A person who violates the provisions of this act or an order
2 of the commissioner shall be liable for the first offense to a civil
3 penalty, to be established by the commissioner, of not less than
4 \$100 nor more than \$1,000, and for the second and each succeeding
5 offense for a civil penalty of not less than \$500 nor more than
6 \$5,000. For the purposes of this subsection, each violation shall
7 constitute a separate offense. The civil penalty shall be collected in
8 a summary proceeding, brought in the name of the State in a court
9 of competent jurisdiction pursuant to the "Penalty Enforcement Law
10 of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).

11
12 8. A person, other than a semen bank licensed pursuant to
13 section 3 of P.L. , c. (C.) (pending before the Legislature as
14 this bill), who sells, offers for sale, or otherwise transfers or seeks
15 to transfer for valuable consideration, human semen, is guilty of a
16 crime of the third degree except that, notwithstanding the provisions
17 of N.J.S.2C:43-3 or any other law, a fine of up to \$50,000 may be
18 imposed on the person.

19
20 9. The Commissioner of Health, pursuant to the
21 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
22 seq.), shall adopt rules and regulations to effectuate the purposes of
23 this act.

24
25 10. This act shall take effect on the first day of the seventh
26 month next following the date of enactment, but the Commissioner
27 of Health may take such anticipatory administrative action in
28 advance thereof as shall be necessary for the implementation of this
29 act.

30 31 32 STATEMENT

33
34 This bill provides for the regulation of semen banks and semen
35 donation in New Jersey.

36 The bill provides specifically as follows:

- 37 • A person is not to operate or conduct a semen bank in this State
38 unless licensed by the Commissioner of Health under the
39 provisions of the bill.
- 40 • The commissioner is to charge a fee for each license or its
41 renewal in an amount determined by the commissioner to be
42 reasonably necessary to cover the cost to the Department of
43 Health of carrying out the provisions of the bill, but the fee may
44 vary based on the number of collections made by a facility.
- 45 • A license is to be issued to any person who has been conducting a
46 semen bank prior to the effective date of the bill upon submission
47 of a properly completed application on a form and in a manner
48 prescribed by the commissioner, including documentation to the

- 1 satisfaction of the commissioner that the semen bank is accredited
2 by the American Association of Tissue Banks and is in
3 compliance with federal regulations, and payment of the
4 application fee.
- 5 • The commissioner, before refusing to grant a license, or before
6 suspending or revoking a license previously granted, except as
7 hereinafter provided in the bill, is to: give notice to the applicant
8 or licensee personally, or by mail addressed to that person at the
9 person's last known address; and afford that person an
10 opportunity to be heard with respect thereto at a time and place
11 specified in the notice.
 - 12 • A license issued in accordance with the provisions of the bill may
13 be suspended or revoked by the commissioner for a violation of
14 any of the provisions of the bill or any rules or regulations
15 adopted pursuant thereto.
 - 16 • A licensee is not to collect semen without having first obtained
17 the following from the prospective donor, on a form and in a
18 manner prescribed by the commissioner:
 - 19 -- a completed registration statement which sets forth the name
20 and address of the donor and contains such other information as
21 prescribed by regulation of the commissioner or required pursuant
22 to federal regulations; and
 - 23 -- a donor information sharing statement as set forth in the bill.
 - 24 • The commissioner is to establish standards of operation for semen
25 banks, including standards for the collection, processing, storage,
26 and distribution of semen, in consultation with the American
27 Association of Tissue Banks and the American Society for
28 Reproductive Medicine, and may incorporate by reference the
29 requirements or guidelines adopted by those entities, as well as
30 federal regulations, in the standards adopted pursuant to the bill.
 - 31 • The commissioner is to impose a limit on semen donations by an
32 individual donor in accordance with recommendations of the
33 American Society for Reproductive Medicine.
 - 34 • A semen bank is to report the information contained in the
35 completed registration statement that it obtains for each donor to
36 the New Jersey Semen Donor Registry established under the bill,
37 and to check with the registry prior to obtaining each donation of
38 semen from any donor.
 - 39 • The donor information sharing statement, required pursuant to the
40 bill, is to specify the level of information that is to be shared with
41 an individual 18 years of age or older if that individual submits a
42 written, notarized request to obtain information pursuant to the
43 bill. The donor may, in the future, ask to update and submit a
44 revised statement to the semen bank, which is to report this
45 information to the New Jersey Semen Donor Registry.
 - 46 • The donor information sharing statement is to specify the
47 following options, from which the donor may select one:

- 1 -- "Complete information sharing" means a donor consents to the
- 2 release of the donor's name, last known address, and telephone
- 3 number, if available;
- 4 -- "Intermediary information sharing only" means a donor does
- 5 not consent to the release of the above information, but agrees to
- 6 communication with the individual requesting the information
- 7 through a third party designated by the donor on the original or
- 8 revised statement;
- 9 -- "Medical information sharing only" means a donor does not
- 10 consent to the release of the above information, but agrees to
- 11 periodic communication limited to the sharing of non-identifying
- 12 family medical history information, with the individual requesting
- 13 the information through a third party designated by the donor on the
- 14 original or revised statement.
- 15 • The licensee is to maintain a copy of the completed and any
- 16 revised donor information sharing statement.
- 17 • An individual who is 18 years of age or older may submit to the
- 18 registry a written, notarized request for information about the
- 19 person whom the individual has reason to believe was a donor.
- 20 -- If the donor submitted a donor information sharing statement
- 21 specifying "complete information sharing," the registry is to provide
- 22 that donor information to the requester.
- 23 -- If the donor submitted a donor information sharing statement
- 24 specifying "intermediary information sharing only," the registry is
- 25 to inform the requester of the donor's wish to communicate with the
- 26 requester through the third party designated by the donor on the
- 27 donor information sharing statement.
- 28 -- If the donor submitted a donor information sharing statement
- 29 specifying "medical information sharing only," the registry is to
- 30 inform the requester of the donor's wish for periodic
- 31 communication limited to the sharing of non-identifying family
- 32 medical history information with the requester through a third party
- 33 designated by the donor on the donor information sharing statement.
- 34 -- If the donor submits a revised statement to the semen bank that
- 35 is reported to the registry pursuant to the bill, the registry is to share
- 36 information with the requester based on the revised statement in
- 37 accordance with the provisions of the bill.
- 38 • The commissioner is to establish and operate a Statewide registry,
- 39 to be designated as the New Jersey Semen Donor Registry, which
- 40 shall be the repository for information obtained from semen
- 41 banks pursuant to the bill.
- 42 -- The commissioner is to adopt regulations for the
- 43 implementation, operation, and evaluation of the registry, including,
- 44 but not limited to, regulations that prescribe the manner for a semen
- 45 bank to submit information to, and obtain information from, the
- 46 registry, and establish procedures to ensure the accuracy and
- 47 confidentiality of information submitted to the registry.

- 1 -- The commissioner may contract with a public or private entity
2 to implement or operate the registry.
- 3 -- All information collected or developed by the registry that
4 identifies or could be used to identify a person is to be considered
5 confidential information, subject to the provisions of the bill, and is
6 to be treated as such by a semen bank, and not be subject to civil or
7 administrative subpoena or discovery in a civil action, including,
8 but not limited to, a judicial, administrative, arbitration, or
9 mediation proceeding.
- 10 -- A person who reports information to the registry or acts on
11 information obtained from the registry in good faith, and in
12 accordance with the provisions of the bill and the rules and
13 regulations adopted pursuant thereto, is immune from any civil or
14 criminal liability that might otherwise be incurred or imposed with
15 respect to those actions.
- 16 • The commissioner is authorized to enter and inspect any semen
17 bank and to make such investigation of the premises and the
18 books and records as is reasonably necessary to carry out the
19 provisions of the bill.
 - 20 • If the commissioner has reason to believe that a condition exists
21 or has occurred at a semen bank, in violation of the provisions of
22 the bill, which is dangerous to the public health, the
23 commissioner may order that semen bank to correct the violation
24 and may suspend the license of the semen bank until the
25 correction is completed. The licensee may apply to the
26 commissioner for a hearing to contest the suspension, and the
27 hearing will be held and a decision rendered within 72 hours of
28 the receipt of the licensee's request. If the commissioner rules
29 against the licensee, the licensee may apply for injunctive relief
30 against the commissioner's order.
 - 31 • A person who violates the provisions of the bill or an order of the
32 commissioner is liable for the first offense to a civil penalty, to be
33 established by the commissioner, of not less than \$100 nor more
34 than \$1,000, and for the second and each succeeding offense for a
35 civil penalty of not less than \$500 nor more than \$5,000, which is
36 to be collected in a summary proceeding, brought in the name of
37 the State in a court of competent jurisdiction pursuant to the
38 "Penalty Enforcement Law of 1999."
 - 39 • A person, other than a semen bank licensed pursuant to this bill,
40 who sells, offers for sale, or otherwise transfers or seeks to
41 transfer for valuable consideration, human semen, is guilty of a
42 crime of the third degree and, notwithstanding the provisions of
43 N.J.S.2C:43-3 or any other law, a fine of up to \$50,000 may be
44 imposed on the person.
 - 45 • The bill takes effect on the first day of the seventh month after
46 enactment, but authorizes the commissioner to take administrative
47 action in advance as necessary for its implementation.