ASSEMBLY, No. 3260

STATE OF NEW JERSEY
218th LEGISLATURE

INTRODUCED FEBRUARY 12, 2018

Sponsored by:
Assemblywoman VALERIE VAINIERI HUTTLE
District 37 (Bergen)

SYNOPSIS
“Reproductive Donation Safety Act.”

CURRENT VERSION OF TEXT
As introduced.
AN ACT concerning the regulation of semen banks and supplementing Title 26 of the Revised Statutes and Title 2C of the New Jersey Statutes.

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

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

2. As used in this act:
   “Assisted reproductive technology” means clinical treatments and laboratory procedures that are performed with the intent of establishing a pregnancy.
   “Collection” means the obtaining of semen from donors.
   “Commissioner” means the Commissioner of Health.
   “Department” means the Department of Health.
   “Distribution” means the removal of semen from a semen bank to any other location for processing or storage or for the purpose of providing the semen for reproductive or research purposes.
   “Donor” means an individual who donates semen from that individual to a semen bank for use in assisted reproductive technology procedures.
   “Federal regulations” means regulations adopted by the federal Food and Drug Administration as set forth at 21 CFR Part 1271 governing human reproductive tissue banks and any other federal regulations that may apply to the operation of semen banks.
   “Licensee” means a person holding a license under the provisions of this act.
   “Person” means a natural person or a partnership, association, corporation, institution, agency, or other similar type of entity.
   “Processing” means the technical stages required to prepare and identify semen as to its suitability.
   “Registry” means the New Jersey Semen Donor Registry established pursuant to section 6 of this act.
   “Semen bank” means a commercial or noncommercial activity involving the handling of human semen that participates in the collection, processing, storage, or distribution of semen for use in assisted reproductive technology procedures.
   “Storage” means the holding of semen in connection with collection or processing prior to distribution.

3. a. A person shall not operate or conduct a semen bank in this State unless licensed by the commissioner under the provisions of this act. The license required by this act shall be in addition to any other license or permit required by a local board of health or other body exercising the powers of such a board in a municipality in this State.
b. The commissioner shall not license a person to operate or conduct a semen bank pursuant to this act unless the commissioner is satisfied that the applicant for licensure has demonstrated good character, competency, and integrity, and the applicant shall furnish such information to the commissioner as the commissioner may require for this purpose.

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

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

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

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

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

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

(2) (a) The commissioner, before refusing to grant a license, or before suspending or revoking a license previously granted, except as hereinafter provided in this act, shall give notice to the applicant or licensee personally, or by mail addressed to that person at the person's last known address, and shall afford that person an opportunity to be heard with respect thereto at a time and place specified in the notice. The applicant or licensee shall have the
right to be heard in person or by an attorney, and to offer evidence
pertinent to the subject of the hearing.

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

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

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

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

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

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

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

(a) qualifications for personnel employed in a semen bank;
(b) restrictions upon the use of semen donors;
(c) standards for collection, processing, storage, and distribution
of semen; and

(d) evaluation of the performance of semen banks.

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

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

5. a. (1) The donor information sharing statement, required
pursuant to section 4 of this act, shall specify the level of
information that shall be shared with an individual 18 years of age
or older if that individual submits a written, notarized request to
obtain information pursuant to subsection d. of this section.
(2) The donor may, in the future, ask to update and submit a
revised statement to the semen bank, which shall report this
information to the New Jersey Semen Donor Registry.
b. The donor information sharing statement shall specify the
following options, from which the donor may select one:
(1) "Complete information sharing" means a donor consents to
the release of the donor’s name, last known address, and telephone
number, if available;
(2) "Intermediary information sharing only" means a donor does
not consent to the release of the information set forth in paragraph
(1) of this subsection, but agrees to communication with the
individual requesting the information through a third party
designated by the donor on the original or revised statement;
(3) "Medical information sharing only" means a donor does not
consent to the release of the information set forth in paragraph (1)
of this subsection, but agrees to periodic communication limited to
the sharing of non-identifying family medical history information,
with the individual requesting the information through a third party
designated by the donor on the original or revised statement.
c. The licensee shall maintain a copy of the completed and any
revised donor information sharing statement.
d. (1) An individual who is 18 years of age or older may submit
to the registry a written, notarized request for information about the
person whom the individual has reason to believe was a donor.
(2) If the donor submitted a donor information sharing statement
specifying "complete information sharing," the registry shall
provide that donor information to the requester.
(3) If the donor submitted a donor information sharing statement
specifying "intermediary information sharing only," the registry
shall inform the requester of the donor's wish to communicate with
the requester through the third party designated by the donor on the
donor information sharing statement.
(4) If the donor submitted a donor information sharing statement
specifying "medical information sharing only," the registry shall
inform the requester of the donor’s wish for periodic
communication limited to the sharing of non-identifying family
medical history information with the requester through a third party
designated by the donor on the donor information sharing statement.
(5) If the donor submits a revised statement to the semen bank
that is reported to the registry pursuant to paragraph (2) of
subsection a. of this section, the registry shall share information
with the requester based on the revised statement in accordance
with the provisions of this section.
6. a. The commissioner shall establish and operate a Statewide registry, to be designated as the New Jersey Semen Donor Registry, which shall be the repository for information obtained from semen banks pursuant to sections 4 and 5 of this act.

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

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

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

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

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

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

c. If the commissioner has reason to believe that a condition exists or has occurred at a semen bank, in violation of the provisions of this act, which is dangerous to the public health, the commissioner may order that semen bank to correct the violation and may suspend the license of the semen bank until the correction is completed. If a licensee denies that a violation exists or has occurred, the licensee shall have the right to apply to the commissioner for a hearing, in which case the hearing shall be held and a decision rendered within 72 hours of the receipt of the licensee’s request. If the commissioner rules against the licensee, the licensee shall have the right to apply to the Superior Court for injunctive relief against the commissioner’s order.
d. A person who violates the provisions of this act or an order of the commissioner shall be liable for the first offense to a civil penalty, to be established by the commissioner, of not less than $100 nor more than $1,000, and for the second and each succeeding offense for a civil penalty of not less than $500 nor more than $5,000. For the purposes of this subsection, each violation shall constitute a separate offense. The civil penalty shall be collected in a summary proceeding, brought in the name of the State in a court of competent jurisdiction pursuant to the “Penalty Enforcement Law of 1999,” P.L.1999, c.274 (C.2A:58-10 et seq.).

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

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

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

STATEMENT

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

The bill provides specifically as follows:

- A person is not to operate or conduct a semen bank in this State unless licensed by the Commissioner of Health under the provisions of the bill.
- The commissioner is to charge a fee for each license or its renewal in an amount determined by the commissioner to be reasonably necessary to cover the cost to the Department of Health of carrying out the provisions of the bill, but the fee may vary based on the number of collections made by a facility.
- A license is to be issued to any person who has been conducting a semen bank prior to the effective date of the bill upon submission of a properly completed application on a form and in a manner prescribed by the commissioner, including documentation to the
satisfaction of the commissioner that the semen bank is accredited
by the American Association of Tissue Banks and is in
compliance with federal regulations, and payment of the
application fee.
• The commissioner, before refusing to grant a license, or before
suspending or revoking a license previously granted, except as
hereinafter provided in the bill, is to: give notice to the applicant
or licensee personally, or by mail addressed to that person at the
person’s last known address; and afford that person an
opportunity to be heard with respect thereto at a time and place
specified in the notice.
• A license issued in accordance with the provisions of the bill may
be suspended or revoked by the commissioner for a violation of
any of the provisions of the bill or any rules or regulations
adopted pursuant thereto.
• A licensee is not to collect semen without having first obtained
the following from the prospective donor, on a form and in a
manner prescribed by the commissioner:
-- a completed registration statement which sets forth the name
and address of the donor and contains such other information as
prescribed by regulation of the commissioner or required pursuant
to federal regulations; and
-- a donor information sharing statement as set forth in the bill.
• The commissioner is to establish standards of operation for semen
banks, including standards for the collection, processing, storage,
and distribution of semen, in consultation with the American
Association of Tissue Banks and the American Society for
Reproductive Medicine, and may incorporate by reference the
requirements or guidelines adopted by those entities, as well as
federal regulations, in the standards adopted pursuant to the bill.
• The commissioner is to impose a limit on semen donations by an
individual donor in accordance with recommendations of the
American Society for Reproductive Medicine.
• A semen bank is to report the information contained in the
completed registration statement that it obtains for each donor to
the New Jersey Semen Donor Registry established under the bill,
and to check with the registry prior to obtaining each donation of
semen from any donor.
• The donor information sharing statement, required pursuant to the
bill, is to specify the level of information that is to be shared with
an individual 18 years of age or older if that individual submits a
written, notarized request to obtain information pursuant to the
bill. The donor may, in the future, ask to update and submit a
revised statement to the semen bank, which is to report this
information to the New Jersey Semen Donor Registry.
• The donor information sharing statement is to specify the
following options, from which the donor may select one:
-- "Complete information sharing" means a donor consents to the release of the donor’s name, last known address, and telephone number, if available;
-- "Intermediary information sharing only" means a donor does not consent to the release of the above information, but agrees to communication with the individual requesting the information through a third party designated by the donor on the original or revised statement;
-- "Medical information sharing only" means a donor does not consent to the release of the above information, but agrees to periodic communication limited to the sharing of non-identifying family medical history information, with the individual requesting the information through a third party designated by the donor on the original or revised statement.

• The licensee is to maintain a copy of the completed and any revised donor information sharing statement.
• An individual who is 18 years of age or older may submit to the registry a written, notarized request for information about the person whom the individual has reason to believe was a donor.
-- If the donor submitted a donor information sharing statement specifying "complete information sharing," the registry is to provide that donor information to the requester.
-- If the donor submitted a donor information sharing statement specifying "intermediary information sharing only," the registry is to inform the requester of the donor’s wish to communicate with the requester through the third party designated by the donor on the donor information sharing statement.
-- If the donor submitted a donor information sharing statement specifying "medical information sharing only," the registry is to inform the requester of the donor’s wish for periodic communication limited to the sharing of non-identifying family medical history information with the requester through a third party designated by the donor on the donor information sharing statement.
-- If the donor submits a revised statement to the semen bank that is reported to the registry pursuant to the bill, the registry is to share information with the requester based on the revised statement in accordance with the provisions of the bill.

• The commissioner is to establish and operate a Statewide registry, to be designated as the New Jersey Semen Donor Registry, which shall be the repository for information obtained from semen banks pursuant to the bill.
-- The commissioner is to adopt regulations for the implementation, operation, and evaluation of the registry, including, but not limited to, regulations that prescribe the manner for a semen bank to submit information to, and obtain information from, the registry, and establish procedures to ensure the accuracy and confidentiality of information submitted to the registry.
The commissioner may contract with a public or private entity to implement or operate the registry.

All information collected or developed by the registry that identifies or could be used to identify a person is to be considered confidential information, subject to the provisions of the bill, and is to be treated as such by a semen bank, and not be subject to civil or administrative subpoena or discovery in a civil action, including, but not limited to, a judicial, administrative, arbitration, or mediation proceeding.

A person who reports information to the registry or acts on information obtained from the registry in good faith, and in accordance with the provisions of the bill and the rules and regulations adopted pursuant thereto, is immune from any civil or criminal liability that might otherwise be incurred or imposed with respect to those actions.

- The commissioner is authorized to enter and inspect any semen bank and to make such investigation of the premises and the books and records as is reasonably necessary to carry out the provisions of the bill.
- If the commissioner has reason to believe that a condition exists or has occurred at a semen bank, in violation of the provisions of the bill, which is dangerous to the public health, the commissioner may order that semen bank to correct the violation and may suspend the license of the semen bank until the correction is completed. The licensee may apply to the commissioner for a hearing to contest the suspension, and the hearing will be held and a decision rendered within 72 hours of the receipt of the licensee’s request. If the commissioner rules against the licensee, the licensee may apply for injunctive relief against the commissioner’s order.
- A person who violates the provisions of the bill or an order of the commissioner is liable for the first offense to a civil penalty, to be established by the commissioner, of not less than $100 nor more than $1,000, and for the second and each succeeding offense for a civil penalty of not less than $500 nor more than $5,000, which is to be collected in a summary proceeding, brought in the name of the State in a court of competent jurisdiction pursuant to the “Penalty Enforcement Law of 1999.”
- A person, other than a semen bank licensed pursuant to this bill, who sells, offers for sale, or otherwise transfers or seeks to transfer for valuable consideration, human semen, is guilty of a crime of the third degree and, notwithstanding the provisions of N.J.S.2C:43-3 or any other law, a fine of up to $50,000 may be imposed on the person.
- The bill takes effect on the first day of the seventh month after enactment, but authorizes the commissioner to take administrative action in advance as necessary for its implementation.