**As Introduced**

**132nd General Assembly**
**Regular Session** **S. B. No. 344**
**2017-2018**

**Senator Schiavoni**
**Cosponsors: Senators Thomas, Williams, Yuko**

# A BILL

To enact sections 3702.37, 3702.371, 3702.372, 3702.373, 3702.374, 3702.375, 3702.376, 3702.377, 3702.378, 3702.379, 3702.99, and 3702.991 of the Revised Code regarding the operation of cryostorage facilities.

## BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

**Section 1.** That sections 3702.37, 3702.371, 3702.372, 3702.373, 3702.374, 3702.375, 3702.376, 3702.377, 3702.378, 3702.379, 3702.99, and 3702.991 of the Revised Code be enacted to read as follows:

**Sec. 3702.37.** (A) As used in sections 3702.37 to 3702.379 of the Revised Code:

(1) "Cryostorage facility" means a facility that stores reproductive tissues intended for the treatment of infertility or the preservation of fertility. "Cryostorage facility" does not mean a facility that stores reproductive tissues only for a scientific research or law enforcement purpose.

(2) "Emergency" includes a blizzard, earthquake, fire, flood, power outage, snowstorm, or tornado.

(3) "Reproductive tissues" means gametes, embryos, and other reproductive tissues from a human source.

(4) "Personnel" means all of the following:

(a) An individual employed by a cryostorage facility in a full-time, part-time, or temporary position;

(b) An individual who works at a cryostorage facility due to being referred to the facility by an employment service;

(c) An individual who works at a cyrostorage facility as an independent contractor.

(5) "Qualified contact" means a member of a cryostorage facility's personnel who meets both of the following requirements:

(a) The personnel member must have completed training that enables the personnel member to respond to a notification provided under an external notification system required by division (C)(2) of this section and take measures appropriate to the situation, including, as necessary, transferring reproductive tissues to a properly functioning cryostorage tank and documenting the transfer.

(b) The personnel member must reside at a location from which the personnel member is able to arrive at the cryostorage facility in not more than twenty-five minutes.

(B) Each cryostorage facility shall comply with all of the following requirements:

(1) The cryostorage facility must be equipped with all of the following:

(a) Adequate ventilation systems;

(b) A low oxygen alarm system;

(c) Devices for monitoring the temperature, and levels of liquid nitrogen, inside cryostorage tanks in use at the facility;

(d) An alarm system that meets the requirements specified in division (C) of this section.

(2) The monitoring devices required by division (B)(1)(c) of this section must be checked in both of the following manners:

(a) Visually at least twice each day in person by qualified personnel of the cryostorage facility during the facility's regular business hours;

(b) At least once each year by a qualified external accrediting entity or inspection agency acceptable to the department of health.

(3) The monitoring devices required by division (B)(1)(c) of this section must be connected to a backup power supply.

(4) If an external backup generator is used for the backup power supply required by division (B)(3) of this section, the external backup generator must undergo preventative maintenance and servicing by a third party at least once each year and an embryology supervisor or laboratory director who is a member of the cryostorage facility's personnel must review and document the maintenance and servicing.

(5) If an external power pack is used for the backup power supply required by division (B)(3) of this section, the external power pack must be checked at least once each week to ensure it has sufficient charge and an embryology supervisor or laboratory

director who is a member of the cryostorage facility's personnel must review and document the check.

(6) The alarm system required by division (B)(1)(d) of this section must be tested as part of a quality control program at least once each week.

(7) Each alarm system test required by division (B)(6) of this section must be documented in the cryostorage facility's records and an embryology supervisor or laboratory director who is a member of the facility's personnel must review and sign the test documentation at least once each month.

(8) Backups for cryostorage tanks in use at the cryostorage facility must be available for immediate use at the facility, including either of the following:

(a) At least one cryostorage tank that has a storage capacity that is at least equal to the cryostorage tank that has the largest storage capacity of the cyrostorage tanks in use at the facility;

(b) Available storage space in other cryostorage tanks at the facility in an amount at least equal to the storage space used by all samples of reproductive tissue stored in the largest cryostorage tank in use at the facility.

(9) The cryostorage facility must have a valid contract with another entity that provides for a properly functioning cryostorage tank to be delivered to the facility as a loan not later than forty-eight hours after a cryostorage tank in use at the facility ceases to function properly.

(10) If a cryostorage tank in use at the cryostorage facility ceases to function properly, the facility must do both of the following until a properly functioning cyrostorage tank

is delivered to the facility in accordance with division (B)(9) of this section and placed into use at the facility:

(a) Manually fill the liquid nitrogen used for the cyrostorage tank that has ceased to function properly;

(b) Manually maintain the temperature inside that tank within a safe range.

(11) Before a cryostorage tank begins to be used to store reproductive tissue at the cryostorage facility, all of the following requirements must be met:

(a) The tank must undergo a documented validation process to ensure that it functions properly.

(b) The validation process must include the taking of direct measurements to assess how much of the tank's liquid nitrogen is depleted over a preset duration.

(c) An embryology supervisor or laboratory director who is a member of the facility's personnel must review and sign the documentation of the validation process.

(12) Adequate amounts of liquid nitrogen used for cryostorage tanks in use at the cryostorage facility must be available at the facility at all times.

(13) Except as provided in division (D) of this section, both of the following requirements must be met if the cryostorage facility stores multiple samples of reproductive tissues from the same client:

(a) If the facility stores five or more samples of reproductive tissues from the same client, the samples must be stored in separate cryostorage tanks.

(b) If the facility stores at least two but less than five samples of reproductive tissues from the same client, the facility must offer the client the option of having the samples stored in separate cryostorage tanks subject to the client's payment of an additional storage fee.

(C) An alarm system required by division (B)(1)(d) of this section must meet both of the following requirements:

(1) The alarm system must be able to produce a signal audible to individuals at the facility whenever at least one of the following happens to a cryostorage tank in use at the cryostorage facility:

(a) The temperature inside the tank rises above a preset threshold or falls below a safe range.

(b) The level of liquid nitrogen inside the tank falls below a safe range.

(c) The tank's mass changes in a manner indicating a problem with the tank.

(2) The alarm system must include an external notification system that provides for the notification of at least a primary qualified contact and, if the primary qualified contact does not respond to the notification, a secondary qualified contact whenever the alarm system detects a problem specified in division (C)(1) of this section.

(D) The requirement of division (B)(13) of this section regarding multiple samples of reproductive tissue from the same client does not apply to any reproductive tissue the cryostorage facility stores on the day immediately preceding the effective date of this section.

(E) In addition to being subject to a fine under division (A) of section 3702.99 of the Revised Code, a cyrostorage facility shall refund to a client any out-of-pocket costs the client has incurred in having reproductive tissues stored at the facility if the reproductive tissue is made nonviable due to the facility's failure to comply with any requirement of division (B) of this section.

**Sec. 3702.371.** Each cryostorage facility shall require all of its personnel whose duties include handling liquid nitrogen to complete, before handling liquid nitrogen, safety training in handling liquid nitrogen.

**Sec. 3702.372.** (A) Each cryostorage facility shall do all of the following to avoid or mitigate the damage to, or destruction of, reproductive tissues stored at the facility that an emergency could cause or causes:

(1) Develop an emergency preparedness plan;

(2) Include as a component of the plan an automated system for quickly notifying by telephone the facility's personnel who work at the facility when there is an emergency at the facility;

(3) Distribute the plan to the facility's personnel who work at the facility;

(4) Test the component of the plan required by division (A)(2) of this section at least once each month;

(5) In a manner consistent with division (B) of this section, require the facility's personnel who work at the facility to participate at least once each year in a test implementation of all other components of the plan;

(6) Contract with a third party for the emergency transfer

and storage of the reproductive tissues in accordance with the plan.

(B) The role of each member of the cryostorage facility's personnel in a test implementation of an emergency preparedness plan under division (A)(5) of this section shall be consistent with the personnel member's regular duties. The facility shall review the results of each test to identify both of the following:

(1) Impediments to the personnel member's abilities to perform their assigned tasks under the plan;

(2) Improvements that should be made to the plan or its implementation.

**Sec. 3702.373.** (A) Each cryostorage facility shall do both of the following:

(1) If reproductive tissues stored at the facility are transferred to another location due to an emergency, provide the facility's clients who are affected by the transfer notice of the transfer, the new location of the tissues, and the status of the tissues not later than fourteen days after the transfer is completed;

(2) If a client's reproductive tissues that are stored at the facility are damaged or destroyed due to equipment failure, provide the client notice of the damage or destruction not later than one week after the facility learns of the damage or destruction and document the damage or destruction in the client's record.

(B) Each contract that a cryostorage facility enters into with a client to store the client's reproductive tissue shall include a provision that explains the facility's duty to provide

notice to the client under divisions (A)(1) and (2) of this section.

(C) A cryostorage facility shall maintain in a client's records the client's preferred method for receiving from the facility the notices required by divisions (A)(1) and (2) of this section. If the facility is unable to use a client's preferred method of receiving a notice, the facility shall attempt to provide the notice to the client through an alternative method.

(D) A cryostorage facility shall document in a client's record each effort the facility makes to provide the client notice under divisions (A)(1) and (2) of this section and the results of each such effort.

(E) A cryostorage facility that provides to a client a notice required by division (A)(1) or (2) of this section shall inform the client of other cryostorage facilities at which the client may have reproductive tissue stored if the facility is unable to continue to store the client's reproductive tissue and the client wants to continue having the reproductive tissue stored. At the request of the client and the client's payment of a transfer fee, the facility shall promptly transfer the client's records and reproductive tissues to any other cryostorage facility the client chooses.

**Sec. 3702.374.** (A) Each cryostorage facility shall do all of the following:

(1) Maintain both of the following:

(a) Records that enable the facility to identify each client's reproductive tissues stored at the facility;

(b) Laboratory log books and other records of the proper

identification and disposition of all reproductive tissues stored at the facility that identify all of the facility's clinical and laboratory personnel who have handled the reproductive tissues to which the log books and records pertain.

(2) Require a laboratory supervisor or director who is a member of the facility's personnel to review and sign the log books and other records required by division (A)(1)(b) of this section at least once each month;

(3) Subject to division (B) of this section, copy the records and log books required by divisions (A)(1)(a) and (b) of this section not less often than required by rules adopted under section 3702.379 of the Revised Code;

(4) Comply with all applicable state and federal laws governing the confidentiality of client records, including the health information privacy provisions of the "Health Insurance Portability and Accountability Act of 1996," 42 U.S.C. 1320d et seq.

(B) For the purpose of division (A)(3) of this section, the copies of the records and log books required by divisions (A)(1)(a) and (b) of this section may be digital copies, if the digital copies are maintained on a secure web site accessible to the cryostorage facility and backups of the digital copies are made not less often than required by rules adopted under section 3702.379 of the Revised Code. Regardless of the form in which the copies of the records and log books are maintained, the copies shall be kept in a secure location that is neither a room in which reproductive tissue is stored nor the same room in which the original records and log books are maintained.

**Sec. 3702.375.** Each cryostorage facility shall report to

the department of health instances of compromised cryostorage tanks and other events that adversely impact reproductive tissues stored at the facility. The reports shall be made in accordance with rules adopted under section 3702.379 of the Revised Code.

**Sec. 3702.376.** Each cryostorage facility shall make a good faith effort to obtain liability insurance coverage or a surety or fidelity bond that meets standards established in rules adopted under section 3702.379 of the Revised Code. A cryostorage facility that is able to obtain such insurance or bond shall obtain and maintain the insurance or bond.

**Sec. 3702.377.** Each cryostorage facility shall comply with the director of health's enforcement authority under section 3702.378 of the Revised Code.

**Sec. 3702.378.** The director of health shall enforce sections 3702.37 to 3702.377 of the Revised Code and the rules adopted under section 3702.379 of the Revised Code. To enforce those sections and rules, the director may do all of the following:

(A) Inspect cryostorage facilities;

(B) Issue orders to secure compliance with the provisions of sections 3702.37 to 3702.377 of the Revised Code and the rules adopted under section 3702.379 of the Revised Code;

(C) Hold hearings, issue subpoenas, compel testimony, and make adjudications;

(D) If the director has reason to believe that a cryostorage facility has knowingly failed to comply with a requirement of sections 3702.37 to 3702.377 of the Revised Code or a rule adopted under section 3702.379 of the Revised Code,

report the suspected failure to the attorney general, a county prosecutor, or other appropriate law enforcement official.

**Sec. 3702.379.** The director of health shall adopt rules in accordance with Chapter 119. of the Revised Code as necessary to enforce the requirements of sections 3702.37 to 3702.378 of the Revised Code.

**Sec. 3702.99.** (A) A cryostorage facility shall be fined one hundred dollars for each day that the facility fails to satisfy a requirement of division (B) of section 3702.37 of the Revised Code.

(B) A cryostorage facility shall be fined five hundred dollars for each of the facility's personnel who do not complete the safety training in handling liquid nitrogen as required by section 3702.371 of the Revised Code.

(C) A cryostorage facility shall be fined five hundred dollars for the first day that the facility fails to satisfy a requirement of section 3702.372 of the Revised Code and one hundred dollars for each subsequent day that the facility continues to fail to satisfy the requirement.

(D) A cryostorage facility shall be fined five hundred dollars for each requirement of section 3702.373 of the Revised Code that the facility fails to satisfy.

(E) A cryostorage facility shall be fined one thousand dollars for each requirement of section 3702.374 of the Revised Code that the facility fails to satisfy.

(F) A cryostorage facility shall be fined one thousand dollars for each report it fails to make under section 3702.375 of the Revised Code.

(G) If a cryostorage facility is able to obtain liability insurance coverage or a surety or fidelity bond for the purpose of section 3702.376 of the Revised Code, the facility shall be fined one thousand dollars for each day that the facility does not have the liability insurance coverage or surety or fidelity bond.

(H) A cryostorage facility shall be fined one hundred dollars the first time it fails under section 3702.377 of the Revised Code to comply with the director of health's enforcement authority under section 3702.378 of the Revised Code and five hundred dollars each subsequent time it so fails.

**Sec. 3702.991.** All fines collected under section 3702.99 of the Revised Code shall be deposited into the infant vitality fund which is hereby created in the state treasury. The department of health shall use all money in the fund to support a program addressing infant mortality in this state. The program shall have both of the following features:

(A) A multipronged, population health approach to the issue of infant mortality which may include any of the following:

(1) Increasing awareness;

(2) Supporting data collection;

(3) Supporting analysis and interpretation to inform decision making and ensure accountability;

(4) Targeting resources where the need is greatest;

(5) Implementing quality improvement science and programming that is evidence based or based on emerging practices.

(B) Measurable intervention activities regarding infant mortality which may include activities related to any of the following:

(1) Safe sleep;

(2) Community engagement;

(3) Centering pregnancy;

(4) Newborn screening;

(5) Safe birth spacing;

(6) Gestational diabetes;

(7) Smoking cessation;

(8) Breastfeeding;

(9) Care coordination;

(10) Progesterone.