As Introduced

132nd General Assembly

Regular Session 2017-2018

S. B. No. 344

Senator Schiavoni

Cosponsors: Senators Thomas, Williams, Yuko

A BILL

То	enact sections 3702.37, 3702.371, 3702.372,	1
	3702.373, 3702.374, 3702.375, 3702.376,	2
	3702.377, 3702.378, 3702.379, 3702.99, and	3
	3702.991 of the Revised Code regarding the	4
	operation of cryostorage facilities.	5

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

Section 1. That sections 3702.37, 3702.371, 3702.372,	6
3702.373, 3702.374, 3702.375, 3702.376, 3702.377, 3702.378,	7
3702.379, 3702.99, and 3702.991 of the Revised Code be enacted	8
to read as follows:	9
Sec. 3702.37. (A) As used in sections 3702.37 to 3702.379	10
of the Revised Code:	11
(1) "Cryostorage facility" means a facility that stores	12
reproductive tissues intended for the treatment of infertility	13
or the preservation of fertility. "Cryostorage facility" does	14
not mean a facility that stores reproductive tissues only for a	15
scientific research or law enforcement purpose.	16
(2) "Emergency" includes a blizzard, earthquake, fire,	17
flood, power outage, snowstorm, or tornado.	18

(3) "Reproductive tissues" means gametes, embryos, and	19
other reproductive tissues from a human source.	20
(4) "Personnel" means all of the following:	21
(a) An individual employed by a cryostorage facility in a	22
full-time, part-time, or temporary position;	23
(b) An individual who works at a cryostorage facility due	24
to being referred to the facility by an employment service;	25
(c) An individual who works at a cyrostorage facility as	26
an independent contractor.	27
(5) "Qualified contact" means a member of a cryostorage	28
facility's personnel who meets both of the following	29
requirements:	30
(a) The personnel member must have completed training that	31
enables the personnel member to respond to a notification	32
provided under an external notification system required by	33
division (C)(2) of this section and take measures appropriate to	34
the situation, including, as necessary, transferring	35
reproductive tissues to a properly functioning cryostorage tank	36
and documenting the transfer.	37
(b) The personnel member must reside at a location from	38
which the personnel member is able to arrive at the cryostorage	39
facility in not more than twenty-five minutes.	40
(B) Each cryostorage facility shall comply with all of the	41
following requirements:	42
(1) The cryostorage facility must be equipped with all of	43
the following:	44
(a) Adequate ventilation systems;	45

(b) A low oxygen alarm system;	46
(c) Devices for monitoring the temperature, and levels of	47
liquid nitrogen, inside cryostorage tanks in use at the	48
<pre>facility;</pre>	49
(d) An alarm system that meets the requirements specified	50
in division (C) of this section.	51
(2) The monitoring devices required by division (B)(1)(c)	52
of this section must be checked in both of the following	53
<pre>manners:</pre>	54
(a) Visually at least twice each day in person by	55
qualified personnel of the cryostorage facility during the	56
<pre>facility's regular business hours;</pre>	57
(b) At least once each year by a qualified external	58
accrediting entity or inspection agency acceptable to the	59
department of health.	60
(3) The monitoring devices required by division (B)(1)(c)	61
of this section must be connected to a backup power supply.	62
(4) If an external backup generator is used for the backup	63
power supply required by division (B)(3) of this section, the	64
external backup generator must undergo preventative maintenance	65
and servicing by a third party at least once each year and an	66
embryology supervisor or laboratory director who is a member of	67
the cryostorage facility's personnel must review and document	68
the maintenance and servicing.	69
(5) If an external power pack is used for the backup power	70
supply required by division (B)(3) of this section, the external	71
power pack must be checked at least once each week to ensure it	72
has sufficient charge and an embryology supervisor or laboratory	73

director who is a member of the cryostorage facility's personnel	74
must review and document the check.	75
(6) The alarm system required by division (B)(1)(d) of	76
this section must be tested as part of a quality control program	77
at least once each week.	78
(7) Each alarm system test required by division (B)(6) of	79
this section must be documented in the cryostorage facility's	80
records and an embryology supervisor or laboratory director who	81
is a member of the facility's personnel must review and sign the	82
test documentation at least once each month.	83
(8) Backups for cryostorage tanks in use at the	84
cryostorage facility must be available for immediate use at the	85
facility, including either of the following:	86
(a) At least one cryostorage tank that has a storage	87
capacity that is at least equal to the cryostorage tank that has	88
the largest storage capacity of the cyrostorage tanks in use at	89
the facility;	90
(b) Available storage space in other cryostorage tanks at	91
the facility in an amount at least equal to the storage space	92
used by all samples of reproductive tissue stored in the largest	93
cryostorage tank in use at the facility.	94
(9) The cryostorage facility must have a valid contract	95
with another entity that provides for a properly functioning	96
cryostorage tank to be delivered to the facility as a loan not	97
later than forty-eight hours after a cryostorage tank in use at	98
the facility ceases to function properly.	99
(10) If a cryostorage tank in use at the cryostorage	100
facility ceases to function properly, the facility must do both	101
of the following until a properly functioning cyrostorage tank	102

is delivered to the facility in accordance with division (B) (9)	103
of this section and placed into use at the facility:	104
(a) Manually fill the liquid nitrogen used for the	105
cyrostorage tank that has ceased to function properly;	106
(b) Manually maintain the temperature inside that tank	107
within a safe range.	108
(11) Before a cryostorage tank begins to be used to store	109
reproductive tissue at the cryostorage facility, all of the	110
<pre>following requirements must be met:</pre>	111
(a) The tank must undergo a documented validation process	112
to ensure that it functions properly.	113
(b) The validation process must include the taking of	114
direct measurements to assess how much of the tank's liquid	115
nitrogen is depleted over a preset duration.	116
(c) An embryology supervisor or laboratory director who is	117
a member of the facility's personnel must review and sign the	118
documentation of the validation process.	119
(12) Adequate amounts of liquid nitrogen used for	120
cryostorage tanks in use at the cryostorage facility must be	121
available at the facility at all times.	122
(13) Except as provided in division (D) of this section,	123
both of the following requirements must be met if the	124
cryostorage facility stores multiple samples of reproductive	125
tissues from the same client:	126
(a) If the facility stores five or more samples of	127
reproductive tissues from the same client, the samples must be	128
stored in separate cryostorage tanks.	129

(b) If the facility stores at least two but less than five	130
samples of reproductive tissues from the same client, the	131
facility must offer the client the option of having the samples	132
stored in separate cryostorage tanks subject to the client's	133
payment of an additional storage fee.	134
(C) An alarm system required by division (B)(1)(d) of this	135
section must meet both of the following requirements:	136
(1) The alarm system must be able to produce a signal	137
audible to individuals at the facility whenever at least one of	138
the following happens to a cryostorage tank in use at the	139
<pre>cryostorage facility:</pre>	140
(a) The temperature inside the tank rises above a preset	141
threshold or falls below a safe range.	142
(b) The level of liquid nitrogen inside the tank falls	143
below a safe range.	144
(c) The tank's mass changes in a manner indicating a	145
<pre>problem with the tank.</pre>	146
(2) The alarm system must include an external notification	147
system that provides for the notification of at least a primary	148
qualified contact and, if the primary qualified contact does not	149
respond to the notification, a secondary qualified contact	150
whenever the alarm system detects a problem specified in	151
division (C)(1) of this section.	152
(D) The requirement of division (B) (13) of this section	153
regarding multiple samples of reproductive tissue from the same	154
client does not apply to any reproductive tissue the cryostorage	155
facility stores on the day immediately preceding the effective	156
date of this section.	157

(E) In addition to being subject to a fine under division	158
(A) of section 3702.99 of the Revised Code, a cyrostorage	159
facility shall refund to a client any out-of-pocket costs the	160
client has incurred in having reproductive tissues stored at the	161
facility if the reproductive tissue is made nonviable due to the	162
facility's failure to comply with any requirement of division	163
(B) of this section.	164
Sec. 3702.371. Each cryostorage facility shall require all	165
of its personnel whose duties include handling liquid nitrogen	166
to complete, before handling liquid nitrogen, safety training in	167
handling liquid nitrogen.	168
Sec. 3702.372. (A) Each cryostorage facility shall do all	169
of the following to avoid or mitigate the damage to, or	170
destruction of, reproductive tissues stored at the facility that	171
an emergency could cause or causes:	172
(1) Develop an emergency preparedness plan;	173
(2) Include as a component of the plan an automated system	174
for quickly notifying by telephone the facility's personnel who	175
work at the facility when there is an emergency at the facility;	176
(3) Distribute the plan to the facility's personnel who	177
work at the facility;	178
(4) Test the component of the plan required by division	179
(A) (2) of this section at least once each month;	180
(5) In a manner consistent with division (B) of this	181
section, require the facility's personnel who work at the	182
facility to participate at least once each year in a test	183
implementation of all other components of the plan;	184
(6) Contract with a third party for the emergency transfer	185

and storage of the reproductive tissues in accordance with the	186
plan.	187
(B) The role of each member of the cryostorage facility's	188
personnel in a test implementation of an emergency preparedness	189
plan under division (A)(5) of this section shall be consistent	190
with the personnel member's regular duties. The facility shall	191
review the results of each test to identify both of the	192
<pre>following:</pre>	193
(1) Impediments to the personnel member's abilities to	194
perform their assigned tasks under the plan;	195
(2) Improvements that should be made to the plan or its	196
<pre>implementation.</pre>	197
Sec. 3702.373. (A) Each cryostorage facility shall do both	198
of the following:	199
(1) If reproductive tissues stored at the facility are	200
transferred to another location due to an emergency, provide the	201
facility's clients who are affected by the transfer notice of	202
the transfer, the new location of the tissues, and the status of	203
the tissues not later than fourteen days after the transfer is	204
<pre>completed;</pre>	205
(2) If a client's reproductive tissues that are stored at	206
the facility are damaged or destroyed due to equipment failure,	207
provide the client notice of the damage or destruction not later	208
than one week after the facility learns of the damage or	209
destruction and document the damage or destruction in the	210
<pre>client's record.</pre>	211
(B) Each contract that a cryostorage facility enters into	212
with a client to store the client's reproductive tissue shall	213
include a provision that explains the facility's duty to provide	214

notice to the client under divisions (A)(1) and (2) of this	215
section.	216
(C) A cryostorage facility shall maintain in a client's	217
records the client's preferred method for receiving from the	218
facility the notices required by divisions (A)(1) and (2) of	219
this section. If the facility is unable to use a client's	220
preferred method of receiving a notice, the facility shall	221
attempt to provide the notice to the client through an	222
alternative method.	223
(D) A cryostorage facility shall document in a client's	224
record each effort the facility makes to provide the client	225
notice under divisions (A)(1) and (2) of this section and the	226
results of each such effort.	227
(E) A cryostorage facility that provides to a client a_	228
notice required by division (A)(1) or (2) of this section shall	229
inform the client of other cryostorage facilities at which the	230
client may have reproductive tissue stored if the facility is	231
unable to continue to store the client's reproductive tissue and	232
the client wants to continue having the reproductive tissue	233
stored. At the request of the client and the client's payment of	234
a transfer fee, the facility shall promptly transfer the	235
client's records and reproductive tissues to any other	236
cryostorage facility the client chooses.	237
Sec. 3702.374. (A) Each cryostorage facility shall do all	238
of the following:	239
(1) Maintain both of the following:	240
(a) Records that enable the facility to identify each	241
client's reproductive tissues stored at the facility;	242
(b) Laboratory log books and other records of the proper	243

identification and disposition of all reproductive tissues	244
stored at the facility that identify all of the facility's	245
clinical and laboratory personnel who have handled the	246
reproductive tissues to which the log books and records pertain.	247
(2) Require a laboratory supervisor or director who is a	248
member of the facility's personnel to review and sign the log	249
books and other records required by division (A)(1)(b) of this	250
section at least once each month;	251
(3) Subject to division (B) of this section, copy the	252
records and log books required by divisions (A)(1)(a) and (b) of	253
this section not less often than required by rules adopted under	254
section 3702.379 of the Revised Code;	255
(4) Comply with all applicable state and federal laws	256
governing the confidentiality of client records, including the	257
health information privacy provisions of the "Health Insurance	258
Portability and Accountability Act of 1996," 42 U.S.C. 1320d et	259
seq.	260
(B) For the purpose of division (A)(3) of this section,	261
the copies of the records and log books required by divisions	262
(A)(1)(a) and (b) of this section may be digital copies, if the	263
digital copies are maintained on a secure web site accessible to	264
the cryostorage facility and backups of the digital copies are	265
made not less often than required by rules adopted under section	266
3702.379 of the Revised Code. Regardless of the form in which	267
the copies of the records and log books are maintained, the	268
copies shall be kept in a secure location that is neither a room	269
in which reproductive tissue is stored nor the same room in	270
which the original records and log books are maintained.	271
Sec. 3702.375. Each cryostorage facility shall report to	272

the department of health instances of compromised cryostorage	273
tanks and other events that adversely impact reproductive	274
tissues stored at the facility. The reports shall be made in	275
accordance with rules adopted under section 3702.379 of the	276
Revised Code.	277
Sec. 3702.376. Each cryostorage facility shall make a good	278
faith effort to obtain liability insurance coverage or a surety	279
or fidelity bond that meets standards established in rules	280
adopted under section 3702.379 of the Revised Code. A	281
cryostorage facility that is able to obtain such insurance or	282
bond shall obtain and maintain the insurance or bond.	283
Sec. 3702.377. Each cryostorage facility shall comply with	284
the director of health's enforcement authority under section	285
3702.378 of the Revised Code.	286
Sec. 3702.378. The director of health shall enforce	287
sections 3702.37 to 3702.377 of the Revised Code and the rules	288
adopted under section 3702.379 of the Revised Code. To enforce	289
those sections and rules, the director may do all of the	290
<pre>following:</pre>	291
(A) Inspect cryostorage facilities;	292
(B) Issue orders to secure compliance with the provisions	293
of sections 3702.37 to 3702.377 of the Revised Code and the	294
rules adopted under section 3702.379 of the Revised Code;	295
(C) Hold hearings, issue subpoenas, compel testimony, and	296
<pre>make adjudications;</pre>	297
(D) If the director has reason to believe that a	298
cryostorage facility has knowingly failed to comply with a	299
requirement of sections 3702.37 to 3702.377 of the Revised Code	300
or a rule adopted under section 3702.379 of the Revised Code,	301

report the suspected failure to the attorney general, a county	302
prosecutor, or other appropriate law enforcement official.	303
Sec. 3702.379. The director of health shall adopt rules in	304
accordance with Chapter 119. of the Revised Code as necessary to	305
enforce the requirements of sections 3702.37 to 3702.378 of the	306
Revised Code.	307
Sec. 3702.99. (A) A cryostorage facility shall be fined	308
one hundred dollars for each day that the facility fails to	309
satisfy a requirement of division (B) of section 3702.37 of the	310
Revised Code.	311
(B) A cryostorage facility shall be fined five hundred	312
dollars for each of the facility's personnel who do not complete	313
the safety training in handling liquid nitrogen as required by	314
section 3702.371 of the Revised Code.	315
(C) A cryostorage facility shall be fined five hundred	316
dollars for the first day that the facility fails to satisfy a	317
requirement of section 3702.372 of the Revised Code and one	318
hundred dollars for each subsequent day that the facility	319
continues to fail to satisfy the requirement.	320
(D) A cryostorage facility shall be fined five hundred	321
dollars for each requirement of section 3702.373 of the Revised	322
Code that the facility fails to satisfy.	323
(E) A cryostorage facility shall be fined one thousand	324
dollars for each requirement of section 3702.374 of the Revised	325
Code that the facility fails to satisfy.	326
(F) A cryostorage facility shall be fined one thousand	327
dollars for each report it fails to make under section 3702.375	328
of the Revised Code.	329

(G) If a cryostorage facility is able to obtain liability	330
insurance coverage or a surety or fidelity bond for the purpose	331
of section 3702.376 of the Revised Code, the facility shall be	332
fined one thousand dollars for each day that the facility does	333
not have the liability insurance coverage or surety or fidelity	334
bond.	335
(H) A cryostorage facility shall be fined one hundred	336
dollars the first time it fails under section 3702.377 of the	337
Revised Code to comply with the director of health's enforcement	338
authority under section 3702.378 of the Revised Code and five	339
hundred dollars each subsequent time it so fails.	340
Sec. 3702.991. All fines collected under section 3702.99	341
of the Revised Code shall be deposited into the infant vitality	342
fund which is hereby created in the state treasury. The	343
department of health shall use all money in the fund to support	344
a program addressing infant mortality in this state. The program	345
shall have both of the following features:	346
(A) A multipronged, population health approach to the	347
issue of infant mortality which may include any of the	348
<pre>following:</pre>	349
(1) Increasing awareness;	350
(2) Supporting data collection;	351
(3) Supporting analysis and interpretation to inform	352
decision making and ensure accountability;	353
(4) Targeting resources where the need is greatest;	354
(5) Implementing quality improvement science and	355
programming that is evidence based or based on emerging	356
practices.	357

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(10) Progesterone.