



SPONSOR: Sen. Venables & Rep. Lavelle & Rep. Miro;
Sens. Bonini, Booth, Bunting, Lawson, Simpson; Reps.
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Short, Wilson

DELAWARE STATE SENATE
146th GENERAL ASSEMBLY

SENATE BILL NO. 45

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO WOMEN'S HEALTH.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE (Three-fifths of all members elected to each house thereof concurring therein):

1 Section 1. Title.

2 This Act shall be known as the "Women's Health Protection Act."

3 Section 2. Amend Title 16, Delaware Code by adding a new Part XIV Chapter 104 to read as follows:

4 "Part XIV.

5 Chapter 104. Women's Health Protection.

6 §10401. Legislative Findings and Purposes.

7 (a) The Legislature of the State of Delaware finds that:

8 (1) Many abortions are performed in clinics devoted solely to providing abortions and family planning
9 services. Most women who seek abortions at these facilities do not have any relationship with the physician who performs
10 the abortion either before or after the procedure. They do not return to the facility for post-surgical care. In most instances,
11 the woman's only actual contact with the abortion provider occurs simultaneously with the abortion procedure, with little
12 opportunity to ask questions about the procedure, potential complications, and proper follow-up care.

13 (2) Abortion is a unique act. It is an act fraught with consequences for others: for the woman who must
14 live with the implications of her decision; for the spouse, family, and society which must confront the knowledge that these
15 procedures exist, procedures some deem nothing short of an act of violence against innocent human life; and, depending on
16 one's beliefs, for the life or potential life that is aborted.

17 (3) Abortion is an invasive, surgical procedure that can lead to numerous and serious (both short- and
18 long-term) medical complications. Potential complications for abortion include, among others, bleeding, hemorrhage,
19 infection, uterine perforation, uterine scarring, blood clots, cervical tears, incomplete abortion (retained tissue), failure to
20 actually terminate the pregnancy, free fluid in the abdomen, acute abdomen, organ damage, missed ectopic pregnancies,
21 cardiac arrest, sepsis, respiratory arrest, reactions to anesthesia, fertility problems, emotional problems, and even death.

22 (4) The risks for second trimester abortions are greater than for first trimester abortions. The risk of
23 hemorrhage, in particular, is greater, and the resultant complications may require a hysterectomy, other reparative surgery,
24 or a blood transfusion.

25 (5) The State of Delaware has a legitimate concern for the public's health and safety.

26 (6) The State of Delaware has legitimate interests from the outset of pregnancy in protecting the health of
27 women.

28 (7) More specifically, the State of Delaware has a legitimate concern with the health of women who
29 undergo abortions.

30 (8) The State of Delaware has a legitimate interest in seeing to it that abortion, like any other medical
31 procedure, is performed under circumstances that ensure maximum safety for the patient.

32 (9) Since the Supreme Court's decision in *Roe v. Wade*, courts have recognized that for the purposes of
33 regulation, abortion services are rationally distinct from other routine medical services, because of the particular gravitas of
34 the moral, psychological, and familial aspects of the abortion decision.

35 (10) The State of Delaware seeks, by enacting this chapter, to protect women's health and safety by
36 enacting medically-accepted standards for the provision of abortions and for the operation of facilities providing abortions.

37 (b) Based on the finding in subsection (a) of this Section, it is the purpose of this chapter to:

38 (1) To regulate abortion clinics consistent with and to the extent permitted by the decisions of the
39 Supreme Court of the United States and other courts.

40 (2) To provide for the protection of public health through the development, establishment, and
41 enforcement of standards of care in abortion clinics.

42 §10402. Definitions. As used in this Chapter only,

43 (a) 'Abortion' means the act of using or prescribing any instrument, medicine, drug, or any other
44 substance, device, or means with the intent to terminate the clinically diagnosable pregnancy of a woman with
45 knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child.

46 Such use, prescription, or means is not an abortion if done with the intent to:

47 (1) Save the life or preserve the health of the unborn child;

48 (2) Remove a dead unborn child caused by spontaneous abortion; or

49 (3) Remove an ectopic pregnancy.

50 (b) 'Abortion clinic' means a facility, other than an accredited hospital, in which five (5) or
51 more first trimester abortions in any month or any second or third trimester abortions are

52 performed.

53 (c) 'Born alive,' with respect to a member of the species *homo sapiens*, means the complete
54 expulsion or extraction from his or her mother of that member, at any stage of development, who
55 after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord,
56 or definite movement of voluntary muscles, regardless of whether the umbilical cord has been
57 cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced
58 labor, cesarean section, or induced abortion.

59 (d) 'Conception' and 'fertilization' each mean the fusion of the human spermatozoon with
60 a human ovum.

61 (e) 'Department' means the Department of Health and Social Services.

62 (f) 'Director' means the Director of the Division of Public Health.

63 (g) 'Gestation' means the time that has elapsed since the first day of the woman's last menstrual period.

64 (h) 'Licensee' means an individual, a partnership, an association, a limited liability company, or a
65 corporation authorized by the Department of Health and Social Services to operate an abortion clinic.

66 (i) 'Physician' means a person licensed to practice medicine in the State of Delaware. This term includes
67 medical doctors and doctors of osteopathy.

68 (j) 'Unborn child' means the offspring of human beings from conception until birth.

69 §10403. Licensure requirements.

70 (a) Beginning on January 1, 2012, all abortion clinics shall be licensed by the Department. Any existing
71 abortion clinic, as defined by this chapter, shall make application for licensure within one-hundred fifty (150) days
72 of the effective date of this Act.

73 (b) An application for a license shall be made to the Department on forms provided by it and shall contain
74 such information as the Department reasonably requires, which shall include affirmative evidence of ability to
75 comply with such reasonable standards, rules, and regulations as are lawfully prescribed hereunder. Additional
76 information required by the Department shall be supplied on supplemental forms as needed.

77 (c) Following receipt of an application for a license, the Department shall issue a license if the applicant
78 and the facility meet the requirements established by this chapter and the minimum standards, rules, and
79 regulations adopted in pursuance thereof, for a period of one (1) year.

80 (d) A temporary or provisional license may be issued to an abortion clinic for a period of six (6) months
81 in cases where sufficient compliance with minimum standards, rules, and regulations require an extension of time,

82 if a disapproval has not been received from any other state or local agency otherwise authorized to inspect such
83 facilities. The failure to comply must not be detrimental to the health and safety of the public.

84 (e) A license shall apply only to the location and licensee stated on the application and such license, once
85 issued, shall not be transferable from one place to another or from one licensee to another. If the location of the
86 facility is changed, the license shall be automatically revoked. A new application form shall be completed prior to
87 all license renewals.

88 (f) An application for a license or renewal to operate an abortion clinic shall be accompanied by a fee of
89 \$600, which is hereby levied as the license fee for operation of an abortion clinic for a period of one (1) year.

90 (g) Each license issued hereunder shall be for a period of one (1) year from the date of issuance unless
91 sooner revoked, shall be on a form prescribed by the Department, and may be renewed from year to year upon
92 application and payment of the license fee as in the case of procurement of the original license.

93 (h) The Department may deny, suspend, revoke, or refuse to renew a license in any case in which it finds
94 that there has been a substantial failure of the applicant or licensee to comply with the requirements of this Chapter
95 or the minimum standards, rules, and regulations adopted by the Department pursuant to this Chapter. In such
96 case, the Department shall furnish the applicant, or licensee thirty (30) days notice specifying reasons for the
97 action.

98 (i) Any person, applicant, or licensee who feels aggrieved by the action of the Department in denying,
99 suspending, revoking, or refusing to renew a license may appeal the Department's action in accordance with the
100 delay, notice, and other procedures established, pursuant to the Administrative Procedures Act.

101 §10404. Inspections and Investigations.

102 (a) The Department shall establish policies and procedures for conducting pre-licensure and re-licensure
103 inspections of abortion clinics. Prior to issuing or reissuing a license, the Department shall conduct an on-site
104 inspection to ensure compliance with the minimum standards, rules, and regulations promulgated by the
105 Department under the authority of this Chapter.

106 (b) The Department shall also establish policies and procedures for conducting inspections and
107 investigations pursuant to complaints received by the Department and made against any abortion clinic. The
108 Department shall receive, record, and dispose of complaints in accordance with the established policies and
109 procedures.

110 §10405. Minimum standards, rules, and regulations for abortion clinics.

111 The Department shall establish minimum standards, rules, and regulations for the licensing

112 and operation of abortion clinics. Such minimum standards, rules, and regulations become effective upon promulgation in
113 accordance with the procedures specified in the administration procedure act.

114 §10406. Administrative rules for abortion clinics.

115 (a) The Director shall adopt rules for an abortion clinic's physical facilities. At a minimum these rules
116 shall prescribe standards for:

117 (1) Adequate private space that is specifically designated for interviewing, counseling, and
118 medical evaluations.

119 (2) Dressing rooms for staff and patients.

120 (3) Appropriate lavatory areas.

121 (4) Areas for pre-procedure hand washing.

122 (5) Private procedure rooms.

123 (6) Adequate lighting and ventilation for abortion procedures.

124 (7) Surgical or gynecologic examination tables and other fixed equipment.

125 (8) Post-procedure recovery rooms that are supervised, staffed, and equipped to meet the
126 patients' needs.

127 (9) Emergency exits to accommodate a stretcher or gurney.

128 (10) Areas for cleaning and sterilizing instruments.

129 (11) Adequate areas for the secure storage of medical records and necessary equipment and
130 supplies.

131 (12) The display in the abortion clinic, in a place that is conspicuous to all patients, of the clinic's
132 current license issued by the Department.

133 (b) The Director shall adopt rules to prescribe abortion clinic supplies and equipment standards, including
134 supplies and equipment that are required to be immediately available for use in an emergency. At a minimum these
135 rules shall:

136 (1) Prescribe required equipment and supplies, including medications, required for the
137 performance, in an appropriate fashion, of any abortion procedure that the medical staff of the
138 clinic anticipates performing and for monitoring the progress of each patient throughout the
139 procedure and recovery period.

140 (2) Require that the number or amount of equipment and supplies at the clinic is adequate at all
141 times to assure sufficient quantities of clean and sterilized durable equipment and supplies to
142 meet the needs of each patient.

143 (3) Prescribe required equipment, supplies, and medications that shall be available and ready for
144 immediate use in an emergency and requirements for written protocols and procedures to be
145 followed by staff in an emergency, such as the loss of electrical power.

146 (4) Prescribe required equipment and supplies for required laboratory tests and requirements for
147 protocols to calibrate and maintain laboratory equipment at the abortion clinic or operated by
148 clinic staff.

149 (5) Require ultrasound equipment in all abortion clinics.

150 (6) Require that all equipment is safe for the patient and the staff, meets applicable federal
151 standards, and is checked annually to ensure safety and appropriate calibration.

152 (c) The Director shall adopt rules relating to abortion clinic personnel. At a minimum these rules shall
153 require that:

154 (1) The abortion clinic designate a medical director of the abortion clinic who is licensed to
155 practice medicine in the State of Delaware.

156 (2) Physicians performing abortions are licensed to practice medicine in the State of Delaware,
157 demonstrate competence in the procedure(s) involved, and are acceptable to the medical director
158 of the abortion clinic.

159 (3) The employment of at least one physician with admitting privileges at an accredited hospital
160 in this State and within thirty (30) miles of the licensed abortion clinic.

161 (4) Surgical assistants receive training in counseling, patient advocacy, and the specific
162 responsibilities of the services the surgical assistants provide.

163 (5) Volunteers, if any, receive training in the specific responsibilities of the services the
164 volunteers provide, including counseling and patient advocacy as provided in the rules adopted
165 by the Director for different types of volunteers based on their responsibilities.

166 (d) The Director shall adopt rules relating to the medical screening and evaluation of each abortion clinic
167 patient. At a minimum these rules shall require:

168 (1) A medical history including the following:

169 a. Reported allergies to medications, antiseptic solutions, or latex.

- 170 b. Obstetric and gynecologic history.
- 171 c. Past surgeries.
- 172 d. Medication that the patient is currently taking.
- 173 (2) A physical examination including a bimanual examination estimating uterine size
- 174 and palpation of the adnexa.
- 175 (3) The appropriate pre-procedure testing including:
- 176 a. Urine or blood tests for pregnancy, if ordered by a physician.
- 177 b. A test for anemia.
- 178 c. Rh typing, unless reliable written documentation of blood type is available.
- 179 d. Other tests as indicated from the physical examination.
- 180 (4) An ultrasound evaluation for all patients who elect to have an abortion. The rules shall
- 181 require that if a person who is not a physician performs an ultrasound examination, that person
- 182 shall have documented evidence that the person completed a course or other acceptable training
- 183 in the operation of ultrasound equipment as prescribed in rule. A physician or other health care
- 184 professional shall review, at the request of the patient, the ultrasound evaluation results with the
- 185 patient before the abortion procedure is performed, including permitting the patient to view the
- 186 active ultrasound image and learn the probable gestational age of the unborn child.
- 187 (5) That the physician is responsible for estimating the gestational age of the unborn child based
- 188 on the ultrasound examination and obstetric standards in keeping with established standards of
- 189 care regarding the estimation of gestational age as defined in rule and shall write the estimate in
- 190 the patient's medical history. The physician shall keep original prints of each ultrasound
- 191 examination of a patient in the patient's medical history file.
- 192 (e) The Director shall adopt rules relating to the abortion procedure. At a minimum these rules shall
- 193 require:
- 194 (1) That medical personnel are available to all patients throughout the abortion procedure.
- 195 (2) Standards for the safe conduct of abortion procedures that conform to obstetric standards in
- 196 keeping with established standards of care regarding the estimation of gestational age as defined
- 197 in rule.
- 198 (3) Appropriate use of local anesthesia, analgesia, and sedation if ordered by the physician.

199 (4) The use of appropriate precautions, such as the establishment of intravenous access at least
200 for patients undergoing second or third trimester abortions.

201 (5) The use of appropriate monitoring of the vital signs and other defined signs and markers of
202 the patient's status throughout the abortion procedure and during the recovery period until the
203 patient's condition is deemed to be stable in the recovery room.

204 (f) The Director shall adopt rules that prescribe recovery room standards. At a minimum these rules shall
205 require that:

206 (1) Immediate post-procedure care consists of observation in a supervised recovery room for as
207 long as the patient's condition warrants.

208 (2) The clinic arrange hospitalization if any complication beyond the management capability of
209 the staff occurs or is suspected.

210 (3) A licensed health care professional who is trained in the management of the recovery area
211 and is capable of providing basic cardiopulmonary resuscitation and related emergency
212 procedures actively monitors patients in the recovery room.

213 (4) A physician with admitting privileges at an accredited hospital in this state and within thirty
214 (30) miles of the abortion clinic remains on the premises of the abortion clinic until all patients
215 are stable and are ready to leave the recovery room and to facilitate the transfer of emergency
216 cases if hospitalization of the patient or a child born alive is necessary. A physician shall sign the
217 discharge order and be readily accessible and available until the last patient is discharged.

218 (5) A physician discusses RhO(d) immune globulin with each patient for whom it is indicated
219 and assures it is offered to the patient in the immediate post-operative period or that it will be
220 available to her within seventy-two (72) hours after completion of the abortion procedure. If the
221 patient refuses, a refusal form approved by the Department shall be signed by the patient and a
222 witness and included in the medical record.

223 (6) Written instructions with regard to post-abortion coitus, signs of possible complications and
224 problems, and general aftercare are given to each patient. Each patient shall have specific
225 instructions regarding access to medical care for complications, including a telephone number to
226 call for medical emergencies.

227 (7) There is a specified minimum length of time that a patient remains in the recovery
228 room by type of abortion procedure and duration of gestation.

229 (8) The physician assures that a licensed health care professional from the abortion
230 clinic makes a good faith effort to contact the patient by telephone, with the
231 patient's consent, within twenty-four (24) hours after surgery to assess the
232 patient's recovery.

233 (9) Equipment and services are located in the recovery room to provide appropriate
234 emergency resuscitative and life support procedures pending the transfer of the
235 patient or a child born alive to the hospital.

236 (g) The Director shall adopt rules that prescribe standards for follow-up care. At a minimum
237 these rules shall require that:

238 (1) A post-abortion medical visit is offered and, if requested, scheduled for two (2) to three (3)
239 weeks after the abortion procedure, including a medical examination and a review of the results
240 of all laboratory tests.

241 (2) A urine or blood test for pregnancy is obtained at the time of the follow-up visit to rule out
242 continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be appropriately
243 evaluated and a physician who performs abortions shall be consulted.

244 (h) The Director shall adopt rules to prescribe abortion clinic incident reporting. At a minimum these
245 rules shall require that:

246 (1) The abortion clinic records each incident resulting in a patient's or a child born alive's serious
247 injury occurring at an abortion clinic and shall report them in writing to the Department within
248 ten (10) days after the incident. For the purposes of this paragraph, 'serious injury' means an
249 injury that occurs at an abortion clinic and that creates a serious risk of substantial impairment of
250 a major body organ.

251 (2) If a patient's death occurs, other than the death of an unborn child properly reported pursuant
252 to law, the abortion clinic reports it to the Department not later than the next Department work
253 day.

254 (3) Incident reports are filed with the Department and appropriate professional regulatory
255 boards.

256 (i) The Department shall not release personally identifiable patient or physician information.

257 (j) The rules adopted by the Director pursuant to this Chapter do not limit the ability of a physician or
258 other health care professional to advise a patient on any health issue.

259 (k) The provisions of this Chapter and the rules and regulations adopted pursuant hereto shall be in
260 addition to any other laws, rules, and regulations which are applicable to facilities defined as “abortion clinics”
261 under this Chapter.

262 §10407. Criminal Penalties.

263 (a) Whoever operates an abortion clinic as defined in this Chapter without a valid license issued by the
264 Department is guilty of the offense of unlicensed operation of an abortion clinic which shall be a Class F Felony .

265 (b) Any person who intentionally or knowingly violates this Chapter or any rules and regulations adopted
266 under this Chapter is guilty of the offense of Unsafe Abortions which shall be a Class G Felony.

267 §10408. Civil Penalties.

268 (a) Any violation of this Chapter or any rules and regulations adopted under this Chapter may be subject
269 to a civil penalty of up to \$5,000 imposed by the Department and/or the Director.

270 (b) Each day of violation constitutes a separate violation for purposes of assessing civil penalties.

271 (c) In deciding whether and to what extent to impose civil penalties, the Department shall consider the
272 following factors:

273 (1) Gravity of the violation including the probability that death or serious physical harm to a
274 patient or individual will result or has resulted;

275 (2) Size of the population at risk as a consequence of the violation;

276 (3) Severity and scope of the actual or potential harm;

277 (4) Extent to which the provisions of the applicable statutes or regulations were violated;

278 (5) Any indications of good faith exercised;

279 (6) The duration, frequency, and relevance of any previous violations; and

280 (7) Financial benefit received for committing or continuing the violation.

281 (d) The Attorney General may institute a legal action to enforce collection of civil penalties imposed
282 pursuant to this Chapter.

283 §10409. Injunctive Remedies.

284 In addition to any other penalty provided by law, whenever in the judgment of the Director, any person
285 has engaged, or is about to engage, in any acts or practices which constitute, or will constitute, a violation of this Chapter,
286 or any rule or regulation adopted under the provision of this Chapter, the Director shall make application to Chancery Court
287 for an order enjoining such acts and practices, and upon a showing by the Director that such person has engaged, or is about

288 to engage, in any such acts or practices, an injunction, or such other order as may be appropriate shall be granted by such
289 court without bond.”

290 Section 3. Construction.

291 (a) Nothing in this Chapter shall be construed as creating or recognizing a right to abortion.

292 (b) It is not the intention of this Act to make lawful an abortion that is currently unlawful.

293 Section 4. Severability.

294 Any provision of this Act held to be invalid or unenforceable by its terms, or as applied to any person or
295 circumstance, shall be construed so as give it the maximum effect permitted by law, unless such holding shall be one of
296 utter invalidity or unenforceability, in which event such provision shall be deemed severable from here and shall not affect
297 the remainder hereof or the application of such provision to other persons not similarly situated or to other, dissimilar
298 circumstances.

299 Section 5. The Department of Health and Social Services, Division of Public Health shall promulgate regulations
300 necessary to fully implement this Act within four months of enactment.

SYNOPSIS

This Bill enacts a mechanism for the licensure, monitoring, and oversight of abortion clinics in the State of Delaware. It provides that the Division of Public Health inspect and oversee licensure of facilities. In addition to creating criminal penalties for violating the Act, the Division of Public Health is given the authority to seek significant civil penalties and injunctive relief for violating the Act.

Author: Senator Venables