

Amendment No. (for drafter's use only)

CHAMBER ACTION

Senate

House

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1 Representative(s) Gannon offered the following:

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3 **Amendment (with title amendment)**

4 Remove everything after the enacting clause and insert:

5 Section 1. This act may be cited as the "People's Health
6 and Safety Act."

7 Section 2. Section 458.338, Florida Statutes, is created
8 to read:

9 458.338 Powers of agency; rules; disposal of human
10 tissue.--

11 (1) The Department of Health shall have the authority to
12 develop and enforce rules for the health, care, and treatment of
13 persons in physicians' or osteopathic physicians' offices or
14 clinics and for the safe operation of such offices or clinics.

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15 (a) The rules shall be reasonably related to the
16 preservation of the health of the patients.

17 (b) The rules may not impose an unconstitutional burden on
18 a patient's privacy rights including a woman's freedom to decide
19 whether to terminate her pregnancy.

20 (c) The rules shall provide for:

21 1. The performance of surgical procedures only by a
22 licensed physician.

23 2. The making, protection, and preservation of patient
24 records, which shall be treated as medical records under this
25 chapter.

26 (2) For clinics that perform abortions in the first
27 trimester of pregnancy only, these rules shall be comparable to
28 rules that apply to all surgical procedures requiring
29 approximately the same degree of skill and care as the
30 performance of first trimester abortions.

31 (3) For offices and clinics in which abortions and other
32 surgical procedures having patient risks similar to or greater
33 than abortions performed after the first trimester of pregnancy,
34 the agency shall adopt rules pursuant to ss. 120.536(1) and
35 120.54 to implement the provisions of this chapter, including
36 the following:

37 (a) Rules for a physician's or osteopathic physician's
38 office or clinic's physical facilities. At a minimum, these
39 rules shall prescribe standards for:

40 1. Adequate private space that is specifically designated
41 for interviewing, counseling, and medical evaluations.

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42 2. Dressing rooms for staff and patients.

43 3. Appropriate lavatory areas.

44 4. Areas for preprocedure hand washing.

45 5. Private procedure rooms.

46 6. Adequate lighting and ventilation for the procedures.

47 7. Surgical or gynecological examination tables and other
48 fixed equipment.

49 8. Postprocedure recovery rooms that are equipped to meet
50 the patients' needs.

51 9. Emergency exits to accommodate a stretcher or gurney.

52 10. Areas for cleaning and sterilizing instruments.

53 11. Adequate areas for the secure storage of medical
54 records and necessary equipment and supplies.

55 12. The display in the office or clinic, in a place that
56 is conspicuous to all patients, of the physician's or
57 osteopathic physician's and the clinic's current license issued
58 by the department.

59 (b) Rules to prescribe office or clinic supplies and
60 equipment standards, including supplies and equipment that are
61 required to be immediately available for use or in an emergency.
62 At a minimum, these rules shall:

63 1. Prescribe required clean and sterilized equipment and
64 supplies, including medications, required for the conduct, in an
65 appropriate fashion, of any procedure that the medical staff of
66 the office or clinic anticipates performing and for monitoring
67 the progress of each patient throughout the procedure and
68 recovery period.

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69 2. Prescribe required equipment, supplies, and medications
70 that shall be available and ready for immediate use in an
71 emergency and requirements for written protocols and procedures
72 to be followed by staff in an emergency, such as the loss of
73 electrical power.

74 3. Prescribe equipment and supplies for required
75 laboratory tests and requirements for protocols to calibrate and
76 maintain laboratory equipment or equipment operated by office or
77 clinic staff at the office or clinic.

78 4. Require ultrasound equipment in those facilities that
79 provide abortions after 12 weeks' gestation.

80 5. Require that all equipment is safe for the patient and
81 the staff, meets applicable federal standards, and is checked
82 annually to ensure safety and appropriate calibration.

83 (c) Rules relating to medical office or clinic personnel.
84 At a minimum, these rules shall require that:

85 1. A clinic designate a medical director who is licensed
86 to practice medicine and surgery in the state and who has
87 admitting privileges at an accredited hospital in the state that
88 is within 50 miles of the clinic.

89 2. If a physician is not present after a procedure is
90 performed, a registered nurse, licensed practical nurse,
91 advanced registered nurse practitioner, or physician assistant
92 shall be present and remain at the clinic to provide
93 postoperative monitoring and care until the patient is
94 discharged.

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95 3. Surgical assistants receive training in counseling,
96 patient advocacy, and the specific responsibilities associated
97 with the services the surgical assistants provide.

98 4. Volunteers receive training in the specific
99 responsibilities associated with the services the volunteers
100 provide, including counseling and patient advocacy as provided
101 in the rules adopted by the director for different types of
102 volunteers based on their responsibilities.

103 (d) Rules relating to the medical screening and evaluation
104 of each patient. At a minimum, these rules shall require:

105 1. A medical history including reported allergies to
106 medications, antiseptic solutions, or latex; past surgeries; and
107 an obstetric and gynecological history.

108 2. A physical examination, including a bimanual
109 examination estimating uterine size and palpation of the adnexa
110 if an abortion procedure is to be performed.

111 3. The appropriate laboratory tests, including:

112 a. For an abortion in which an ultrasound examination is
113 not performed before the abortion procedure, urine or blood
114 tests for pregnancy performed before the abortion procedure.

115 b. A test for anemia.

116 c. Rh typing, unless reliable written documentation of
117 blood type is available.

118 d. Other tests as indicated from the physical examination.

119 4. An ultrasound evaluation for all patients who elect to
120 have an abortion after 12 weeks' gestation. The rules shall
121 require that if a person who is not a physician performs an

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122 ultrasound examination, that person shall have documented
123 evidence that he or she has completed a course in the operation
124 of ultrasound equipment as prescribed in rule. The physician,
125 registered nurse, licensed practical nurse, advanced registered
126 nurse practitioner, or physician assistant shall review, at the
127 request of the patient, the ultrasound evaluation results,
128 including an estimate of the probable gestational age of the
129 fetus, with the patient before the abortion procedure is
130 performed.

131 5. That the physician is responsible for estimating the
132 gestational age of the fetus based on the ultrasound examination
133 and obstetric standards in keeping with established standards of
134 care regarding the estimation of fetal age as defined in rule
135 and shall write the estimate in the patient's medical history.
136 The physician shall keep original prints of each ultrasound
137 examination of a patient in the patient's medical history file.

138 (e) Rules relating to the surgical procedure. At a
139 minimum, these rules shall require:

140 1. That a physician, registered nurse, licensed practical
141 nurse, advanced registered nurse practitioner, or physician
142 assistant is available to all patients throughout the surgical
143 procedure.

144 2. Standards for the safe conduct of surgical procedures
145 that conform to medical standards in keeping with established
146 standards of care.

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147 3. Appropriate use of general and local anesthesia,
148 analgesia, and sedation if ordered by the physician or
149 osteopathic physician.

150 4. Appropriate precautions, such as the establishment of
151 intravenous access where medically appropriate.

152 5. Appropriate monitoring of the vital signs and other
153 defined signs and markers of the patient's status throughout the
154 surgical procedure and during the recovery period until the
155 patient's condition is deemed to be stable in the recovery room.

156 (f) Rules that prescribe minimum recovery room standards.
157 At a minimum, these rules shall require that:

158 1. Postprocedure recovery rooms are supervised and staffed
159 to meet the patients' needs.

160 2. Immediate postprocedure care consists of observation in
161 a supervised recovery room for as long as the patient's
162 condition warrants.

163 3. The office or clinic arranges hospitalization if any
164 complication beyond the medical capability of the staff occurs
165 or is suspected.

166 4. A registered nurse, licensed practical nurse, advanced
167 registered nurse practitioner, or physician assistant who is
168 trained in the management of the recovery area and is capable of
169 providing basic cardiopulmonary resuscitation and related
170 emergency procedures remains on the premises of the office or
171 clinic until all patients are discharged.

172 5. A physician shall sign the discharge order and be
173 readily accessible and available until the last patient is

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174 discharged to facilitate the transfer of emergency cases if
175 hospitalization of the patient is necessary.

176 6. A physician discusses Rho(D) immune globulin with each
177 patient for whom it is indicated and ensures that it is offered
178 to the patient in the immediate postoperative period or that it
179 will be available to her within 72 hours after completion of the
180 abortion procedure. If the patient refuses the Rho(D) immune
181 globulin, a refusal form approved by the department shall be
182 signed by the patient and a witness and included in the medical
183 record.

184 7. Written instructions with regard to post-procedure
185 coitus, signs of possible problems, and general aftercare are
186 given to each patient. Each patient shall have specific written
187 instructions regarding access to medical care for complications,
188 including a telephone number to call for medical emergencies.

189 8. There is a specified minimum length of time that a
190 patient remains in the recovery room by accepted medical
191 standards.

192 9. The physician or osteopathic physician ensures that a
193 registered nurse, licensed practical nurse, advanced registered
194 nurse practitioner, or physician assistant makes a good faith
195 effort to contact the patient by telephone, with the patient's
196 consent, within 24 hours after surgery to assess the patient's
197 recovery.

198 10. Equipment and services are located in the recovery
199 room to provide appropriate emergency resuscitative and life

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200 support procedures pending the transfer of the patient to the
201 hospital.

202 (g) Rules that prescribe standards for followup care. At a
203 minimum, these rules shall require that a post-surgery medical
204 visit that includes a medical examination and a review of the
205 results of all laboratory tests is offered and, if requested,
206 scheduled for 2 to 3 weeks after the procedure.

207 (h) Rules to prescribe minimum office or clinic incident
208 reporting. At a minimum, these rules shall require that:

209 1. The office or clinic records each incident that results
210 in serious injury to a patient and shall report an incident in
211 writing to the department within 10 days after the incident
212 occurs. For the purposes of this paragraph, "serious injury"
213 means an injury that occurs at an office or clinic and that
214 creates a serious risk of substantial impairment of a major
215 bodily organ or bodily function.

216 2. If a patient's death occurs, other than a fetal death
217 properly reported pursuant to law, the office or clinic reports
218 it to the department not later than the next department workday.

219 3. Incident reports are filed with the department and
220 appropriate professional regulatory boards.

221 (4) The department shall not release personally
222 identifiable patient or physician information.

223 (5) The rules adopted pursuant to this section shall not
224 limit the ability of a physician to advise a patient on any
225 health issue.

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226 (6) The provisions of this section and the rules adopted
227 pursuant hereto shall be in addition to any other laws, rules,
228 and regulations which are applicable to facilities where
229 surgical procedures are performed.

230 (7) The agency may adopt and enforce rules, in the
231 interest of protecting the public health, to ensure the prompt
232 and proper disposal of human tissue resulting from the
233 procedure.

234 (8) If any owner, operator, or employee of an office or
235 clinic fails to dispose of human tissue in a manner consistent
236 with accepted medical standards in a competent professional
237 manner, the license of such office or clinic may be suspended or
238 revoked, and such person is guilty of a misdemeanor of the first
239 degree, punishable as provided in s. 775.082 or s. 775.083.

240 Section 3. If any provision of this act or the application
241 thereof to any person or circumstance is held invalid, the
242 invalidity shall not affect other provisions or applications of
243 the act which can be given effect without the invalid provision
244 or application. To this end, the provisions of this act are
245 declared severable.

246 Section 4. This act shall take effect July 1, 2005.

247
248 ===== T I T L E A M E N D M E N T =====

249 Remove the entire title and insert:

250 A bill to be entitled

251 An act relating to people's health and safety; providing a
252 popular name; creating s. 458.338, F.S.; authorizing the

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HOUSE AMENDMENT

Bill No. HB 1041

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253 Department of Health to develop and enforce rules for the
254 health, care, and treatment of persons in physicians' or
255 osteopathic physicians' offices or clinics and for the safe
256 operation of such offices or clinics; specifying the scope
257 of such rules; providing minimum requirements for such
258 rules; prohibiting the department from releasing certain
259 information; prohibiting the limitation of a physician's
260 ability to advise patients; providing for the continued
261 applicability of current laws, rules, and regulations
262 applicable to certain facilities; authorizing the Agency
263 for Health Care Administration to adopt and enforce certain
264 rules relating to the disposal of human tissue; providing a
265 ground for discipline relating to the disposal of human
266 tissue; providing severability; providing an effective
267 date.

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