

By Senator Grimsley

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1                                   A bill to be entitled  
2       An act relating to advanced birth centers; amending s.  
3       383.30, F.S.; revising the short title; amending s.  
4       383.301, F.S.; providing for the applicability of  
5       licensure requirements under part II of ch. 408, F.S.,  
6       to advanced birth centers; amending s. 383.302, F.S.;  
7       defining the term "advanced birth center"; revising  
8       definitions; amending s. 383.307, F.S.; providing  
9       requirements for the administration of an advanced  
10      birth center; creating s. 383.3081, F.S.; providing  
11      requirements for advanced birth center facilities and  
12      equipment; amending s. 383.309, F.S.; requiring the  
13      Agency for Health Care Administration to adopt by rule  
14      minimum standards for advanced birth centers, which  
15      must be equivalent to specified standards; authorizing  
16      the agency to enforce specified provisions of the  
17      Florida Building Code and the Florida Fire Prevention  
18      Code; requiring an advanced birth center, at a  
19      minimum, to comply with certain construction  
20      standards; amending s. 383.311, F.S.; providing for  
21      the education and orientation of advanced birth center  
22      clients and their families; amending s. 383.312, F.S.;  
23      requiring advanced birth centers to ensure that  
24      clients have adequate prenatal care; amending s.  
25      383.313, F.S.; conforming provisions to changes made  
26      by the act; creating s. 383.3131, F.S.; requiring that  
27      laboratories located in advanced birth centers be  
28      licensed as clinical laboratories; restricting the  
29      surgical procedures that may be provided at advanced

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30 birth centers; providing conditions for the  
31 administration of anesthesia and the use of specified  
32 chemical agents; amending s. 383.315, F.S.; requiring  
33 an advanced birth center to employ or maintain an  
34 agreement with an obstetrician who is available to  
35 attend and perform cesarean deliveries when necessary;  
36 amending s. 383.316, F.S.; requiring advanced birth  
37 centers to provide for the transfer and transport of  
38 emergency patients to a hospital, to identify and list  
39 certain transportation services, and to annually  
40 assess and document certain services and protocols;  
41 amending s. 383.318, F.S.; requiring that mothers and  
42 infants be discharged from an advanced birth center  
43 within specified timeframes except in unusual  
44 circumstances; requiring the filing of a certain  
45 report in such circumstances; providing protocols for  
46 postpartum care of clients and infants; providing  
47 requirements for followup care; amending s. 383.32,  
48 F.S.; specifying that clinical records must be  
49 immediately available at an advanced birth center at  
50 specified times; amending s. 383.332, F.S.; providing  
51 a criminal penalty for operating an unlicensed  
52 advanced birth center; amending s. 465.003, F.S.;  
53 revising the definition of the term "institutional  
54 pharmacy" to include pharmacies located in advanced  
55 birth centers; amending s. 465.019, F.S.; revising the  
56 definition of the term "modified Class II  
57 institutional pharmacies" to include pharmacies  
58 located in advanced birth centers; providing an

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59 effective date.

60  
61 Be It Enacted by the Legislature of the State of Florida:

62  
63 Section 1. Section 383.30, Florida Statutes, is amended to  
64 read:

65 383.30 Birth Center and Advanced Birth Center Licensure  
66 Act; short title.—Sections 383.30-383.335 shall be known and may  
67 be cited as the “Birth Center and Advanced Birth Center  
68 Licensure Act.”

69 Section 2. Section 383.301, Florida Statutes, is amended to  
70 read:

71 383.301 Licensure and regulation of birth centers;  
72 legislative intent.—It is the intent of the Legislature to  
73 provide for the protection of public health and safety in the  
74 establishment, maintenance, and operation of birth centers and  
75 advanced birth centers by providing for licensure of birth  
76 centers and advanced birth centers and for the development,  
77 establishment, and enforcement of minimum standards with respect  
78 to birth centers and advanced birth centers. The requirements of  
79 part II of chapter 408 ~~shall~~ apply to the provision of services  
80 that require licensure pursuant to ss. 383.30-383.335 and part  
81 II of chapter 408 and to entities licensed by or applying for  
82 such licensure from the Agency for Health Care Administration  
83 pursuant to ss. 383.30-383.335. A license issued by the agency  
84 is required in order to operate a birth center or an advanced  
85 birth center in this state.

86 Section 3. Present subsections (1) through (10) of section  
87 383.302, Florida Statutes, are redesignated as subsections (2)

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88 through (11), respectively, present subsections (3), (4), and  
89 (5) are amended, and a new subsection (1) is added to that  
90 section, to read:

91 383.302 Definitions of terms used in ss. 383.30-383.335.—As  
92 used in ss. 383.30-383.335, the term:

93 (1) "Advanced birth center" means a birth center that is  
94 authorized to perform trials of labor after cesarean deliveries  
95 for qualified and screened patients, planned low-risk cesarean  
96 deliveries, and anticipated vaginal deliveries for laboring  
97 patients after the completion of a patient's 36th week of  
98 gestation but prior to the 42nd week of gestation.

99 (4)~~(3)~~ "Clinical staff" means individuals employed full  
100 time or part time by a birth center or an advanced birth center  
101 who are licensed or certified to provide care at childbirth.

102 (5)~~(4)~~ "Consultant" means a physician licensed pursuant to  
103 chapter 458 or chapter 459 who agrees to provide advice and  
104 services to a birth center or an advanced birth center and who  
105 either:

106 (a) Is certified or eligible for certification by the  
107 American Board of Obstetrics and Gynecology;~~7~~ or

108 (b) Has hospital obstetrical privileges.

109 (6)~~(5)~~ "Governing body" means any individual, group,  
110 corporation, or institution which is responsible for the overall  
111 operation and maintenance of a birth center or an advanced birth  
112 center.

113 Section 4. Section 383.307, Florida Statutes, is amended to  
114 read:

115 383.307 Administration of birth center or advanced birth  
116 center.—

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117 (1) Each birth center and advanced birth center shall have  
118 a governing body which is responsible for the overall operation  
119 and maintenance of the ~~birth~~ center.

120 (a) The governing body shall develop and display a table of  
121 organization which shows the structure of the birth center or  
122 advanced birth center and identifies the governing body, the  
123 ~~birth~~ center director, the clinical director, the clinical  
124 staff, and the medical consultant.

125 (b) The governing body shall develop and make available to  
126 staff, clinicians, consultants, and licensing authorities a  
127 manual which documents policies, procedures, and protocols,  
128 including the roles and responsibilities of all personnel.

129 (2) There shall be an adequate number of licensed personnel  
130 to provide clinical services needed by mothers and newborns and  
131 a sufficient number of qualified personnel to provide services  
132 for families and to maintain the birth center or the advanced  
133 birth center.

134 (3) All clinical staff members and consultants shall hold  
135 current licenses from this state to practice their respective  
136 disciplines.

137 (4) Clinical staff members and consultants shall adopt  
138 bylaws which are subject to the approval of the governing body  
139 and which shall include recommendations for clinical staff or  
140 consultation appointments, delineation of clinical privileges,  
141 and the organization of the clinical staff.

142 Section 5. Section 383.3081, Florida Statutes, is created  
143 to read:

144 383.3081 Advanced birth center facility and equipment;  
145 requirements.-

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146       (1) An advanced birth center shall meet all of the  
147 requirements of s. 383.308.

148       (2) An advanced birth center shall be operated and staffed  
149 24 hours a day, 7 days a week.

150       (3) Each advanced birth center shall have at least one  
151 properly equipped, dedicated surgical suite for the performance  
152 of cesarean deliveries.

153       Section 6. Section 383.309, Florida Statutes, is amended to  
154 read:

155       383.309 Minimum standards for birth centers and advanced  
156 birth centers; rules and enforcement.-

157       (1) The agency shall adopt and enforce rules to administer  
158 ss. 383.30-383.335 and part II of chapter 408, which rules shall  
159 include, but are not limited to, reasonable and fair minimum  
160 standards for ensuring that:

161       (a) Sufficient numbers and qualified types of personnel and  
162 occupational disciplines are available at all times to provide  
163 necessary and adequate patient care and safety.

164       (b) Infection control, housekeeping, sanitary conditions,  
165 disaster plan, and medical record procedures that will  
166 adequately protect patient care and provide safety are  
167 established and implemented.

168       (c) Licensed facilities are established, organized, and  
169 operated consistent with established programmatic standards.

170       (2) The agency shall adopt by rule minimum standards for  
171 advanced birth centers which are equivalent to the minimum  
172 standards for ambulatory surgical centers adopted under s.  
173 395.1055. Such standards must include sanitary conditions for  
174 food handling and food service.

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175        (3)~~(2)~~ The agency may not establish any rule governing the  
176 design, construction, erection, alteration, modification,  
177 repair, or demolition of birth centers or advanced birth  
178 centers. It is the intent of the Legislature to preempt that  
179 function to the Florida Building Commission and the State Fire  
180 Marshal through adoption and maintenance of the Florida Building  
181 Code and the Florida Fire Prevention Code. However, the agency  
182 shall provide technical assistance to the commission and the  
183 State Fire Marshal in updating the construction standards of the  
184 Florida Building Code and the Florida Fire Prevention Code which  
185 govern birth centers and advanced birth centers. In addition,  
186 the agency may enforce the special-occupancy provisions of the  
187 Florida Building Code and the Florida Fire Prevention Code which  
188 apply to birth centers or advanced birth centers in conducting  
189 any inspection authorized under this chapter or part II of  
190 chapter 408. At a minimum, an advanced birth center must comply  
191 with the Florida Building Code and the Florida Fire Prevention  
192 Code construction standards for ambulatory surgical centers.

193        Section 7. Section 383.311, Florida Statutes, is amended to  
194 read:

195        383.311 Education and orientation for birth center and  
196 advanced birth center clients and their families.—

197        (1) The clients and their families shall be fully informed  
198 of the policies and procedures of the birth center or advanced  
199 birth center, including, but not limited to, policies and  
200 procedures on:

201            (a) The selection of clients.

202            (b) The expectation of self-help and family/client  
203 relationships.

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- 204 (c) The qualifications of the clinical staff.
- 205 (d) The transfer to secondary or tertiary care.
- 206 (e) The philosophy of childbirth care and the scope of  
207 services.
- 208 (f) The customary length of stay after delivery.
- 209 (2) The clients shall be prepared for childbirth and  
210 childbearing by education in:
- 211 (a) The course of pregnancy and normal changes occurring  
212 during pregnancy.
- 213 (b) The need for prenatal care.
- 214 (c) Nutrition, including encouragement of breastfeeding.
- 215 (d) The effects of smoking and substance abuse.
- 216 (e) Labor and delivery.
- 217 (f) The care of the newborn to include safe sleep practices  
218 and the possible causes of Sudden Unexpected Infant Death.
- 219 Section 8. Section 383.312, Florida Statutes, is amended to  
220 read:
- 221 383.312 Prenatal care of birth center and advanced birth  
222 center clients.—
- 223 (1) A birth center and an advanced birth center shall  
224 ensure that their ~~its~~ clients have adequate prenatal care, as  
225 defined by the agency, and shall ensure that serological tests  
226 are administered as required by this chapter.
- 227 (2) Records of prenatal care shall be maintained for each  
228 client and shall be available during labor and delivery.
- 229 Section 9. Section 383.313, Florida Statutes, is amended to  
230 read:
- 231 383.313 Birth center performance of laboratory and surgical  
232 services; use of anesthetic and chemical agents.—



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233 (1) LABORATORY SERVICES.—A birth center may collect  
234 specimens for those tests that are requested under protocol. A  
235 birth center may perform simple laboratory tests, as defined by  
236 rule of the agency, and is exempt from the requirements of  
237 chapter 483, provided no more than five physicians are employed  
238 by the birth center and testing is conducted exclusively in  
239 connection with the diagnosis and treatment of clients of the  
240 birth center.

241 (2) SURGICAL SERVICES.—Surgical procedures are ~~shall be~~  
242 limited to those normally performed during uncomplicated  
243 childbirths, such as episiotomies and repairs and may ~~shall~~ not  
244 include operative obstetrics or caesarean sections.

245 (3) ADMINISTRATION OF ANALGESIA AND ANESTHESIA.—General and  
246 conduction anesthesia may not be administered at a birth center.  
247 Systemic analgesia may be administered, and local anesthesia for  
248 pudendal block and episiotomy repair may be performed if  
249 procedures are outlined by the clinical staff and performed by  
250 personnel with statutory authority to do so.

251 (4) INTRAPARTAL USE OF CHEMICAL AGENTS.—Labor may not be  
252 inhibited, stimulated, or augmented with chemical agents during  
253 the first or second stage of labor unless prescribed by  
254 personnel with statutory authority to do so and unless in  
255 connection with and prior to emergency transport.

256 Section 10. Section 383.3131, Florida Statutes, is created  
257 to read:

258 383.3131 Advanced birth center performance of laboratory  
259 and surgical services; use of anesthetic and chemical agents.—

260 (1) LABORATORY SERVICES.—A laboratory located in an  
261 advanced birth center must be licensed as a clinical laboratory

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262 under chapter 483.

263 (2) SURGICAL SERVICES.—In addition to surgical procedures  
264 authorized pursuant to s. 383.312(2), an advanced birth center  
265 may only provide surgical procedures related to uncomplicated  
266 cesarean deliveries and the management of immediate  
267 complications. Postpartum sterilization may be performed on a  
268 mother, and circumcision may be performed on an infant, before  
269 discharge.

270 (3) ADMINISTRATION OF ANESTHESIA.—General, conduction, and  
271 local anesthesia may be administered at an advanced birth center  
272 by personnel with statutory authority to do so. All general  
273 anesthesia must be administered by an anesthesiologist or a  
274 certified registered nurse anesthetist in accordance with s.  
275 464.012, and such practitioner must be present in the advanced  
276 birth center at all times during the administration of  
277 anesthesia and during the postanesthesia recovery period until  
278 the patient is fully alert. A board-certified anesthesiologist  
279 must be on call and readily available at all times when  
280 anesthesia services are performed by a certified registered  
281 nurse anesthetist.

282 (4) INTRAPARTAL USE OF CHEMICAL AGENTS.—Labor may be  
283 inhibited, stimulated, or augmented with chemical agents during  
284 the first or second stage of labor if such agents are prescribed  
285 by personnel with statutory authority to do so. Labor may be  
286 induced at 39 or more weeks of gestation if the patient has a  
287 documented Bishop score of 8 or greater.

288 Section 11. Section 383.315, Florida Statutes, is amended  
289 to read:

290 383.315 Agreements with consultants for advice or services;

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291 maintenance.—

292 (1) A birth center and an advanced birth center shall  
293 maintain in writing a consultation agreement, signed within the  
294 current license period, with each consultant who has agreed to  
295 provide advice and services to the birth center or the advanced  
296 birth center as requested.

297 (2) Consultation may be provided onsite or by telephone, as  
298 required by clinical and geographic conditions.

299 (3) An advanced birth center shall employ or maintain an  
300 agreement with an obstetrician who is available to attend and  
301 perform cesarean deliveries when necessary.

302 Section 12. Section 383.316, Florida Statutes, is amended  
303 to read:

304 383.316 Transfer and transport of clients to hospitals.—

305 (1) If unforeseen complications arise during labor,  
306 delivery, or postpartum the client shall be transferred to a  
307 hospital.

308 (2) Each licensed birth center and advanced birth center  
309 ~~facility~~ shall make arrangements with a local ambulance service  
310 licensed under chapter 401 for the transport of emergency  
311 patients to a hospital. Such arrangements shall be documented in  
312 the center's policy and procedures manual ~~of the facility~~ if the  
313 birth center or advanced birth center does not own or operate a  
314 licensed ambulance. The policy and procedures manual shall also  
315 contain specific protocols for the transfer of any patient to a  
316 licensed hospital.

317 (3) A licensed birth center and advanced birth center  
318 ~~facility~~ shall identify neonatal-specific transportation  
319 services, including ground and air ambulances; list their

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320 particular qualifications; and have the telephone numbers for  
321 access to these services clearly listed and immediately  
322 available.

323 (4) The birth center or advanced birth center shall  
324 annually assess and document ~~Annual assessments of the~~  
325 ~~transportation services and transfer protocols shall be made and~~  
326 ~~documented.~~

327 Section 13. Section 383.318, Florida Statutes, is amended  
328 to read:

329 383.318 Postpartum care for birth center and advanced birth  
330 center clients and infants.-

331 (1) A mother and her infant must ~~shall~~ be discharged  
332 ~~dismissed~~ from a ~~the~~ birth center within 24 hours after the  
333 birth of the infant, except in unusual circumstances as defined  
334 by rule of the agency. If a mother or an infant is retained at  
335 the birth center for more than 24 hours after the birth, a  
336 report shall be filed with the agency within 48 hours of the  
337 birth describing the circumstances and the reasons for the  
338 decision.

339 (2) A mother and her infant must be discharged from an  
340 advanced birth center within 48 hours after a vaginal delivery  
341 and within 72 hours after a delivery by cesarean section, except  
342 in unusual circumstances as defined by agency rule. If a mother  
343 or an infant is kept at the advanced birth center for a longer  
344 period of time, a report must be filed with the agency within 48  
345 hours after the scheduled discharge time describing the  
346 circumstances and the reasons for the extended stay.

347 (3) ~~(2)~~ A prophylactic shall be instilled in the eyes of  
348 each newborn in accordance with s. 383.04.

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349        (4)~~(3)~~ Postpartum evaluation and followup care shall be  
350 provided, which must ~~shall~~ include:

351            (a) Physical examination of the infant.

352            (b) Metabolic screening tests required by s. 383.14.

353            (c) Referral to sources for pediatric care.

354            (d) Maternal postpartum assessment.

355            (e) Instruction in child care, including immunization,  
356 breastfeeding, safe sleep practices, and possible causes of  
357 Sudden Unexpected Infant Death.

358            (f) Family planning services.

359            (g) Referral to secondary or tertiary care, as indicated.

360        Section 14. Subsection (2) of section 383.32, Florida  
361 Statutes, is amended to read:

362            383.32 Clinical records.—

363            (2) Clinical records must ~~shall~~ be immediately available at  
364 the birth center or advanced birth center:

365            (a) At the time of admission.

366            (b) When transfer of care is necessary.

367            (c) For audit by licensure personnel.

368        Section 15. Section 383.332, Florida Statutes, is amended  
369 to read:

370            383.332 Establishing, managing, or operating a birth center  
371 or an advanced birth center without a license; penalty.—Any  
372 person who establishes, conducts, manages, or operates any birth  
373 center or advanced birth center ~~facility~~ without a license  
374 issued under s. 383.305 and part II of chapter 408 commits a  
375 misdemeanor and, upon conviction, shall be fined not more than  
376 \$100 for the first offense and not more than \$500 for each  
377 subsequent offense; and each day of continuing violation after

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378 conviction shall be considered a separate offense.

379 Section 16. Paragraph (a) of subsection (11) of section  
380 465.003, Florida Statutes, is amended to read:

381 465.003 Definitions.—As used in this chapter, the term:

382 (11) (a) "Pharmacy" includes a community pharmacy, an  
383 institutional pharmacy, a nuclear pharmacy, a special pharmacy,  
384 and an Internet pharmacy.

385 1. The term "community pharmacy" includes every location  
386 where medicinal drugs are compounded, dispensed, stored, or sold  
387 or where prescriptions are filled or dispensed on an outpatient  
388 basis.

389 2. The term "institutional pharmacy" includes every  
390 location in a hospital, clinic, advanced birth center, nursing  
391 home, dispensary, sanitarium, extended care facility, or other  
392 facility, hereinafter referred to as "health care institutions,"  
393 where medicinal drugs are compounded, dispensed, stored, or  
394 sold.

395 3. The term "nuclear pharmacy" includes every location  
396 where radioactive drugs and chemicals within the classification  
397 of medicinal drugs are compounded, dispensed, stored, or sold.  
398 The term "nuclear pharmacy" does not include hospitals licensed  
399 under chapter 395 or the nuclear medicine facilities of such  
400 hospitals.

401 4. The term "special pharmacy" includes every location  
402 where medicinal drugs are compounded, dispensed, stored, or sold  
403 if such locations are not otherwise defined in this subsection.

404 5. The term "Internet pharmacy" includes locations not  
405 otherwise licensed or issued a permit under this chapter, within  
406 or outside this state, which use the Internet to communicate

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407 with or obtain information from consumers in this state and use  
408 such communication or information to fill or refill  
409 prescriptions or to dispense, distribute, or otherwise engage in  
410 the practice of pharmacy in this state. Any act described in  
411 this definition constitutes the practice of pharmacy as defined  
412 in subsection (13).

413 Section 17. Paragraph (c) of subsection (2) of section  
414 465.019, Florida Statutes, is amended to read:

415 465.019 Institutional pharmacies; permits.-

416 (2) The following classes of institutional pharmacies are  
417 established:

418 (c) "Modified Class II institutional pharmacies" are those  
419 institutional pharmacies in short-term, primary care treatment  
420 centers and advanced birth centers which ~~that~~ meet all the  
421 requirements for a Class II permit, except space and equipment  
422 requirements.

423 Section 18. This act shall take effect July 1, 2018.