

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 applicability of licensure
5 requirements under pt. II of ch. 408, F.S., to
6 advanced birth centers; amending s. 383.302, F.S.;
7 defining the term "advanced birth center"; revising
8 definitions; amending s. 383.305, F.S.; providing
9 applicability of licensure fee requirements to
10 advanced birth centers; amending s. 383.307, F.S.;
11 providing for administration of advance birth centers;
12 creating s. 383.3081, F.S.; providing requirements for
13 advanced birth center facilities and equipment;
14 amending s. 383.309, F.S.; providing minimum standards
15 for advanced birth centers; authorizing the Agency for
16 Health Care Administration to enforce specified
17 provisions of the Florida Building Code and the
18 Florida Fire Prevention Code; amending s. 383.3105,
19 F.S.; providing applicability of adoption protocols
20 for staff of an advanced birth center; amending s.
21 383.311, F.S.; providing for the education and
22 orientation of advanced birth center clients and their
23 families; amending s. 383.312, F.S.; providing for an
24 advanced birth center to offer prenatal care; amending
25 s. 383.313, F.S.; providing for laboratory and

26 surgical services at a birth center; creating s.
27 383.3131, F.S.; providing requirements for laboratory
28 and surgical services at an advanced birth center;
29 providing conditions for administration of anesthesia;
30 authorizing the intrapartum use of chemical agents;
31 amending s. 383.315, F.S.; requiring an advanced birth
32 center to employ or maintain an agreement with an
33 obstetrician under certain circumstances; amending s.
34 383.316, F.S.; requiring an advanced birth center to
35 provide for transport of emergency patients to a
36 hospital; amending s. 383.318, F.S.; providing
37 protocols for postpartum care of clients and infants;
38 providing requirements for followup care; amending s.
39 383.324, F.S.; requiring an advanced birth center to
40 pay an inspection fee to the agency; amending s.
41 383.327, F.S.; requiring an advanced birth center to
42 provide reports of all births and deaths occurring at
43 the center; requiring reports to the agency; amending
44 s. 383.33, F.S.; providing for fines, administrative
45 penalties, and moratoriums; amending s. 383.332, F.S.;
46 providing a criminal penalty for operating an
47 unlicensed advanced birth center; amending s. 465.003,
48 F.S.; revising the definition of the term
49 "institutional pharmacy" to include pharmacies located
50 in advanced birth centers; amending s. 465.019, F.S.;

51 revising the definition of the term "modified Class II
52 institutional pharmacies" to include pharmacies
53 located in advanced birth centers; providing an
54 effective date.

55

56 Be It Enacted by the Legislature of the State of Florida:

57

58 Section 1. Section 383.30, Florida Statutes, is amended to
59 read:

60 383.30 Birth Center and Advanced Birth Center Licensure
61 Act; short title.—Sections 383.30–383.335 shall be known and may
62 be cited as the "Birth Center and Advanced Birth Center
63 Licensure Act."

64 Section 2. Section 383.301, Florida Statutes, is amended
65 to read:

66 383.301 Licensure and regulation of birth centers and
67 advanced birth centers; legislative intent.—It is the intent of
68 the Legislature to provide for the protection of public health
69 and safety in the establishment, maintenance, and operation of
70 birth centers and advanced birth centers by providing for
71 licensure of birth centers and advanced birth centers and for
72 the development, establishment, and enforcement of minimum
73 standards with respect to birth centers and advanced birth
74 centers. The requirements of part II of chapter 408 shall apply
75 to the provision of services that require licensure pursuant to

76 ss. 383.30-383.335 and part II of chapter 408 and to entities
 77 licensed by or applying for such licensure from the Agency for
 78 Health Care Administration pursuant to ss. 383.30-383.335. A
 79 license issued by the agency is required in order to operate a
 80 birth center or an advanced birth center in this state.

81 Section 3. Subsections (1) through (10) of section
 82 383.302, Florida Statutes, are renumbered as subsections (2)
 83 through (11), respectively, present subsections (3), (4), and
 84 (5) are amended, and a new subsection (1) is added to that
 85 section, to read:

86 383.302 Definitions of terms used in ss. 383.30-383.335.—
 87 As used in ss. 383.30-383.335, the term:

88 (1) "Advanced birth center" means a birth center that may
 89 perform trial of labor after cesarean deliveries for screened
 90 patients that qualify, planned low-risk cesarean deliveries, and
 91 anticipated vaginal deliveries for laboring patients from the
 92 beginning of the 37th week of gestation through the end of the
 93 41st week of gestation.

94 (4)~~(3)~~ "Clinical staff" means individuals employed full
 95 time or part time by a birth center or an advanced birth center
 96 who are licensed or certified to provide care at childbirth.

97 (5)~~(4)~~ "Consultant" means a physician licensed pursuant to
 98 chapter 458 or chapter 459 who agrees to provide advice and
 99 services to a birth center or an advanced birth center and who
 100 either:

101 (a) Is certified or eligible for certification by the
 102 American Board of Obstetrics and Gynecology, or

103 (b) Has hospital obstetrical privileges.

104 ~~(6)-(5)~~ "Governing body" means any individual, group,
 105 corporation, or institution which is responsible for the overall
 106 operation and maintenance of a birth center or an advanced birth
 107 center.

108 Section 4. Section 383.305, Florida Statutes, is amended
 109 to read:

110 383.305 Licensure; fees.—

111 (1) In accordance with s. 408.805, an applicant for
 112 licensure as a birth center or an advanced birth center or a
 113 licensee shall pay a fee for each license application submitted
 114 under ss. 383.30-383.335 and part II of chapter 408. The amount
 115 of the fee shall be established by rule.

116 (2) Each applicant for licensure and each licensee must
 117 comply with the requirements of this chapter and part II of
 118 chapter 408.

119 Section 5. Section 383.307, Florida Statutes, is amended
 120 to read:

121 383.307 Administration of birth center and advanced birth
 122 center.—

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

126 (a) The governing body shall develop and display a table
127 of organization which shows the structure of the birth center or
128 advanced birth center and identifies the governing body, the
129 ~~birth center~~ director, the clinical director, the clinical
130 staff, and the medical consultant.

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

135 (2) There shall be an adequate number of licensed
136 personnel to provide clinical services needed by mothers and
137 newborns and a sufficient number of qualified personnel to
138 provide services for families and to maintain the birth center
139 or the advanced birth center.

140 (3) All clinical staff members and consultants shall hold
141 current licenses from this state to practice their respective
142 disciplines.

143 (4) Clinical staff members and consultants shall adopt
144 bylaws which are subject to the approval of the governing body
145 and which shall include recommendations for clinical staff or
146 consultation appointments, delineation of clinical privileges,
147 and the organization of the clinical staff.

148 Section 6. Section 383.3081, Florida Statutes, is created
149 to read:

150 383.3081 Advanced birth center facility and equipment;

151 requirements.-

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

154 (2) An advanced birth center shall be operated and staffed
155 24 hours per day, 7 days per week.

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

159 Section 7. Section 383.309, Florida Statutes, is amended
160 to read:

161 383.309 Minimum standards for birth centers and advanced
162 birth centers; rules and enforcement.-

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

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

170 (b) Infection control, housekeeping, sanitary conditions,
171 disaster plan, and medical record procedures that will
172 adequately protect patient care and provide safety are
173 established and implemented.

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

176 (2) Minimum standards adopted by rule for advanced birth
177 centers must be equivalent to the minimum standards adopted for
178 ambulatory surgical centers pursuant to s. 395.1055 and shall
179 include sanitary conditions for food handling and food service.

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

198 Section 8. Section 383.3105, Florida Statutes, is amended
199 to read:

200 383.3105 Patients consenting to adoptions; protocols.—

201 (1) Each licensed birth center and advanced birth center
202 ~~facility~~ shall adopt a protocol that at a minimum provides for
203 birth center and advanced birth center ~~facility~~ staff to be
204 knowledgeable of the waiting periods, revocation and the
205 contents of the consent to adoption as contained in s.
206 63.082(4), and describes the supportive and unbiased manner in
207 which ~~facility~~ staff will interact with birth parents and
208 prospective adoptive parents regarding the adoption, in
209 particular during the waiting period required in s. 63.082(4)(b)
210 before consenting to an adoption.

211 (2) The protocol shall be in writing and be provided upon
212 request to any birth parent or prospective adoptive parent of a
213 child born in the birth center and advanced birth center
214 ~~facility~~.

215 Section 9. Section 383.311, Florida Statutes, is amended
216 to read:

217 383.311 Education and orientation for birth center and
218 advanced birth center clients and their families.—

219 (1) The clients and their families shall be fully informed
220 of the policies and procedures of the birth center or advanced
221 birth center, including, but not limited to, policies and
222 procedures on:

223 (a) The selection of clients.

224 (b) The expectation of self-help and family/client
225 relationships.

- 226 (c) The qualifications of the clinical staff.
- 227 (d) The transfer to secondary or tertiary care.
- 228 (e) The philosophy of childbirth care and the scope of
229 services.
- 230 (f) The customary length of stay after delivery.
- 231 (2) The clients shall be prepared for childbirth and
232 childbearing by education in:
- 233 (a) The course of pregnancy and normal changes occurring
234 during pregnancy.
- 235 (b) The need for prenatal care.
- 236 (c) Nutrition, including encouragement of breastfeeding.
- 237 (d) The effects of smoking and substance abuse.
- 238 (e) Labor and delivery.
- 239 (f) The care of the newborn to include safe sleep
240 practices and the possible causes of Sudden Unexpected Infant
241 Death.
- 242 Section 10. Section 383.312, Florida Statutes, is amended
243 to read:
- 244 383.312 Prenatal care of birth center and advanced birth
245 center clients.—
- 246 (1) A birth center and an advanced birth center shall
247 ensure that their ~~its~~ clients have adequate prenatal care, as
248 defined by the agency, and shall ensure that serological tests
249 are administered as required by this chapter.
- 250 (2) Records of prenatal care shall be maintained for each

251 client and shall be available during labor and delivery.

252 Section 11. Section 383.313, Florida Statutes, is amended
253 to read:

254 383.313 Birth center performance of laboratory and
255 surgical services; use of anesthetic and chemical agents.—

256 (1) LABORATORY SERVICES.—A birth center may collect
257 specimens for those tests that are requested under protocol. A
258 birth center may perform simple laboratory tests, as defined by
259 rule of the agency, and is exempt from the requirements of
260 chapter 483, provided no more than five physicians are employed
261 by the birth center and testing is conducted exclusively in
262 connection with the diagnosis and treatment of clients of the
263 birth center.

264 (2) SURGICAL SERVICES.—Surgical procedures shall be
265 limited to those normally performed during uncomplicated
266 childbirths, such as episiotomies and repairs and may ~~shall~~ not
267 include operative obstetrics or caesarean sections.

268 (3) ADMINISTRATION OF ANALGESIA AND ANESTHESIA.—General
269 and conduction anesthesia may not be administered at a birth
270 center. Systemic analgesia may be administered, and local
271 anesthesia for pudendal block and episiotomy repair may be
272 performed if procedures are outlined by the clinical staff and
273 performed by personnel with statutory authority to do so.

274 (4) INTRAPARTAL USE OF CHEMICAL AGENTS.—Labor may not be
275 inhibited, stimulated, or augmented with chemical agents during

276 the first or second stage of labor unless prescribed by
277 personnel with statutory authority to do so and unless in
278 connection with and prior to emergency transport.

279 Section 12. Section 383.3131, Florida Statutes, is created
280 to read:

281 383.3131 Advanced birth center performance of laboratory
282 and surgical services; use of anesthetic and chemical agents.—

283 (1) LABORATORY SERVICES.—An advanced birth center may
284 collect specimens for those tests that are requested under
285 protocol. An advanced birth center may perform laboratory tests,
286 as defined by rule of the agency. Laboratories located in
287 advanced birth centers must be licensed as a clinical laboratory
288 under chapter 483.

289 (2) SURGICAL SERVICES.—In addition to surgical procedures
290 authorized pursuant to s. 383.313(2), surgical procedures are
291 limited to uncomplicated cesarean section deliveries and
292 surgical management of immediate complications. Postpartum
293 sterilization may be performed prior to discharge of the patient
294 who has given birth during that admission. Circumcisions may be
295 performed prior to discharge of the newborn infant.

296 (3) ADMINISTRATION OF ANALGESIA AND ANESTHESIA.—General,
297 conduction, and local anesthesia may be administered at an
298 advanced birth center if administered by personnel with the
299 statutory authority to do so. All general anesthesia shall be
300 administered by an anesthesiologist or a certified registered

301 nurse anesthetist in accordance with s. 464.012. When general
302 anesthesia is administered, a physician or a certified
303 registered nurse anesthetist shall be present in the advanced
304 birth center during the anesthesia and postanesthesia recovery
305 period until the patient is fully alert.

306 (4) INTRAPARTAL USE OF CHEMICAL AGENTS.—Labor may be
307 inhibited, stimulated, or augmented with chemical agents during
308 the first or second stage of labor at an advanced birth center
309 if prescribed by personnel with statutory authority to do so.
310 Labor may be electively induced beginning at the 39th week of
311 gestation for a patient with a documented Bishop score of 8 or
312 greater.

313 Section 13. Section 383.315, Florida Statutes, is amended
314 to read:

315 383.315 Agreements with consultants for advice or
316 services; maintenance.—

317 (1) A birth center and an advanced birth center shall
318 maintain in writing a consultation agreement, signed within the
319 current license period, with each consultant who has agreed to
320 provide advice and services to the birth center and advanced
321 birth center as requested.

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

324 (3) An advanced birth center shall either employ or
325 maintain an agreement with an obstetrician to be available to

326 attend and available to perform cesarean section deliveries,
327 when necessary.

328 Section 14. Section 383.316, Florida Statutes, is amended
329 to read:

330 383.316 Transfer and transport of clients to hospitals.—

331 (1) If unforeseen complications arise during labor,
332 delivery, or postpartum recovery, the client shall be
333 transferred to a hospital.

334 (2) Each licensed birth center or advanced birth center
335 ~~facility~~ shall make arrangements with a local ambulance service
336 licensed under chapter 401 for the transport of emergency
337 patients to a hospital. Such arrangements shall be documented in
338 the policy and procedures center's manual ~~of the facility~~ if the
339 birth center or advanced birth center does not own or operate a
340 licensed ambulance. The policy and procedures manual shall also
341 contain specific protocols for the transfer of any patient to a
342 licensed hospital.

343 (3) A licensed birth center or advanced birth center
344 ~~facility~~ shall identify neonatal-specific transportation
345 services, including ground and air ambulances; list their
346 particular qualifications; and have the telephone numbers for
347 access to these services clearly listed and immediately
348 available.

349 (4) The birth center or advanced birth center shall assess
350 and document ~~Annual assessments of~~ the transportation services

351 and transfer protocols annually ~~shall be made and documented.~~

352 Section 15. Section 383.318, Florida Statutes, is amended
353 to read:

354 383.318 Postpartum care for birth center and advanced
355 birth center clients and infants.-

356 (1) A mother and her infant shall be dismissed from a ~~the~~
357 birth center within 24 hours after the birth of the infant,
358 except in unusual circumstances as defined by rule of the
359 agency. If a mother or an infant is retained at the birth center
360 for more than 24 hours after the birth, a report shall be filed
361 with the agency within 48 hours of the birth describing the
362 circumstances and the reasons for the decision.

363 (2) (a) A mother and her infant shall be discharged from an
364 advanced birth center within 48 hours after the birth of the
365 infant for a vaginal delivery and within 72 hours when delivery
366 is by cesarean section, except in unusual circumstances defined
367 by rule of the agency.

368 (b) If a mother or an infant is retained at the advanced
369 birth center for more than the timeframes set forth in paragraph
370 (a), a report shall be filed with the agency within 48 hours
371 after the scheduled discharge time describing the circumstances
372 and the reasons for the decision.

373 (3) ~~(2)~~ A prophylactic shall be instilled in the eyes of
374 each newborn in accordance with s. 383.04.

375 (4) ~~(3)~~ Postpartum evaluation and followup care shall be

376 | provided, which shall include:

- 377 | (a) Physical examination of the infant.
- 378 | (b) Metabolic screening tests required by s. 383.14.
- 379 | (c) Referral to sources for pediatric care.
- 380 | (d) Maternal postpartum assessment.
- 381 | (e) Instruction in child care, including immunization,
- 382 | breastfeeding, safe sleep practices, and possible causes of
- 383 | Sudden Unexpected Infant Death.

- 384 | (f) Family planning services.
- 385 | (g) Referral to secondary or tertiary care, as indicated.

386 | Section 16. Section 383.324, Florida Statutes, is amended
387 | to read:

388 | 383.324 Inspections and investigations; inspection fees.—
389 | Each birth center and advanced birth center ~~facility~~ licensed
390 | under s. 383.305 shall pay to the agency an inspection fee
391 | established by rule of the agency. In addition to the
392 | requirements of part II of chapter 408, the agency shall
393 | coordinate all periodic inspections for licensure made by the
394 | agency to ensure that the cost to the birth center and advanced
395 | birth center ~~facility~~ of such inspections and the disruption of
396 | services by such inspections is minimized.

397 | Section 17. Section 383.327, Florida Statutes, is amended
398 | to read:

399 | 383.327 Birth and death records; reports.—Each licensed
400 | birth center and advanced birth center shall:

401 (1) File a completed certificate of birth ~~shall be filed~~
 402 with the local registrar within 5 days of each birth in
 403 accordance with chapter 382.

404 (2) Immediately report each maternal death, newborn death,
 405 and stillbirth ~~shall be reported immediately~~ to the medical
 406 examiner.

407 (3) ~~The licensee shall~~ Comply with all requirements of
 408 this chapter and rules promulgated hereunder.

409 (4) Annually submit a report ~~shall be submitted annually~~
 410 to the agency. The contents of the report shall be prescribed by
 411 rule of the agency.

412 Section 18. Section 383.33, Florida Statutes, is amended
 413 to read:

414 383.33 Administrative penalties; moratorium on
 415 admissions.—

416 (1) In addition to the requirements of part II of chapter
 417 408, the agency may impose an administrative fine not to exceed
 418 \$500 per violation per day for the violation of any provision of
 419 ss. 383.30-383.335, part II of chapter 408, or applicable rules.

420 (2) In determining the amount of the fine to be levied for
 421 a violation, as provided in this section, the following factors
 422 shall be considered:

423 (a) The severity of the violation, including the
 424 probability that death or serious harm to the health or safety
 425 of any person will result or has resulted; the severity of the

426 actual or potential harm; and the extent to which the provisions
427 of ss. 383.30-383.335, part II of chapter 408, or applicable
428 rules were violated.

429 (b) Actions taken by the licensee to correct the
430 violations or to remedy complaints.

431 (c) Any previous violations by the licensee.

432 (3) In accordance with part II of chapter 408, the agency
433 may impose an immediate moratorium on elective admissions to any
434 licensed birth center or advanced birth center ~~facility~~,
435 building or portion thereof, or service when the agency
436 determines that any condition in the center ~~facility~~ presents a
437 threat to the public health or safety.

438 Section 19. Section 383.332, Florida Statutes, is amended
439 to read:

440 383.332 Establishing, managing, or operating a birth
441 center or an advanced birth center without a license; penalty.-
442 Any person who establishes, conducts, manages, or operates any
443 birth center or advanced birth center ~~facility~~ without a license
444 issued under s. 383.305 and part II of chapter 408 commits a
445 misdemeanor and, upon conviction, shall be fined not more than
446 \$100 for the first offense and not more than \$500 for each
447 subsequent offense; and each day of continuing violation after
448 conviction shall be considered a separate offense.

449 Section 20. Subsection (11) of section 465.003, Florida
450 Statutes, is amended to read:

451 465.003 Definitions.—As used in this chapter, the term:

452 (11) (a) "Pharmacy" includes a community pharmacy, an
 453 institutional pharmacy, a nuclear pharmacy, a special pharmacy,
 454 and an Internet pharmacy.

455 1. The term "community pharmacy" includes every location
 456 where medicinal drugs are compounded, dispensed, stored, or sold
 457 or where prescriptions are filled or dispensed on an outpatient
 458 basis.

459 2. The term "institutional pharmacy" includes every
 460 location in a hospital, clinic, advanced birth center, nursing
 461 home, dispensary, sanitarium, extended care facility, or other
 462 facility, hereinafter referred to as "health care institutions,"
 463 where medicinal drugs are compounded, dispensed, stored, or
 464 sold.

465 3. The term "nuclear pharmacy" includes every location
 466 where radioactive drugs and chemicals within the classification
 467 of medicinal drugs are compounded, dispensed, stored, or sold.
 468 The term "nuclear pharmacy" does not include hospitals licensed
 469 under chapter 395 or the nuclear medicine facilities of such
 470 hospitals.

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

474 5. The term "Internet pharmacy" includes locations not
 475 otherwise licensed or issued a permit under this chapter, within

476 or outside this state, which use the Internet to communicate
477 with or obtain information from consumers in this state and use
478 such communication or information to fill or refill
479 prescriptions or to dispense, distribute, or otherwise engage in
480 the practice of pharmacy in this state. Any act described in
481 this definition constitutes the practice of pharmacy as defined
482 in subsection (13).

483 (b) The pharmacy department of any permittee shall be
484 considered closed whenever a Florida licensed pharmacist is not
485 present and on duty. The term "not present and on duty" shall
486 not be construed to prevent a pharmacist from exiting the
487 prescription department for the purposes of consulting or
488 responding to inquiries or providing assistance to patients or
489 customers, attending to personal hygiene needs, or performing
490 any other function for which the pharmacist is responsible,
491 provided that such activities are conducted in a manner
492 consistent with the pharmacist's responsibility to provide
493 pharmacy services.

494 Section 21. Paragraph (c) of subsection (2) of section
495 465.019, Florida Statutes, is amended to read:

496 465.019 Institutional pharmacies; permits.—

497 (2) The following classes of institutional pharmacies are
498 established:

499 (c) "Modified Class II institutional pharmacies" are those
500 institutional pharmacies in short-term, primary care treatment

501 | centers and advanced birth centers that meet all the
502 | requirements for a Class II permit, except space and equipment
503 | requirements.

504 | Section 22. This act shall take effect July 1, 2018.