

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	<u> </u>	(Y/N)
ADOPTED AS AMENDED	<u> </u>	(Y/N)
ADOPTED W/O OBJECTION	<u> </u>	(Y/N)
FAILED TO ADOPT	<u> </u>	(Y/N)
WITHDRAWN	<u> </u>	(Y/N)
OTHER	<u> </u>	

1 Committee/Subcommittee hearing bill: Health Quality
2 Subcommittee

3 Representative Magar offered the following:

4

5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 383.30, Florida Statutes, is amended to
8 read:

9 383.30 Birth Center and Advanced Birth Center Licensure
10 Act; short title.—Sections 383.30–383.335 shall be known and may
11 be cited as the "Birth Center and Advanced Birth Center
12 Licensure Act."

13 Section 2. Section 383.301, Florida Statutes, is amended
14 to read:

15 383.301 Licensure and regulation of birth centers and
16 advanced birth centers; legislative intent.—It is the intent of

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17 the Legislature to provide for the protection of public health
18 and safety in the establishment, maintenance, and operation of
19 birth centers and advanced birth centers by providing for
20 licensure of birth centers and advanced birth centers and for
21 the development, establishment, and enforcement of minimum
22 standards with respect to birth centers and advanced birth
23 centers. The requirements of part II of chapter 408 shall apply
24 to the provision of services that require licensure pursuant to
25 ss. 383.30-383.335 and part II of chapter 408 and to entities
26 licensed by or applying for such licensure from the Agency for
27 Health Care Administration pursuant to ss. 383.30-383.335. A
28 license issued by the agency is required in order to operate a
29 birth center or an advanced birth center in this state.

30 Section 3. Subsections (1) through (10) of section
31 383.302, Florida Statutes, are renumbered as subsections (2)
32 through (11), respectively, present subsections (3), (4), (5),
33 and (8) are amended, and a new subsection (1) is added to that
34 section, to read:

35 383.302 Definitions of terms used in ss. 383.30-383.335.—
36 As used in ss. 383.30-383.335, the term:

37 (1) "Advanced birth center" means a birth center which may
38 perform trial of labor after cesarean deliveries for screened
39 patients that qualify, planned low risk cesarean deliveries, and
40 anticipated vaginal delivery of laboring patients at 37 to 41
41 weeks of gestation.

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42 ~~(4)(3)~~ "Clinical staff" means individuals employed full
43 time or part time by a birth center or an advanced birth center
44 who are licensed or certified to provide care at childbirth.

45 ~~(5)(4)~~ "Consultant" means a physician licensed pursuant to
46 chapter 458 or chapter 459 who agrees to provide advice and
47 services to a birth center or an advanced birth center and who
48 either:

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

51 (b) Has hospital obstetrical privileges.

52 ~~(6)(5)~~ "Governing body" means any individual, group,
53 corporation, or institution which is responsible for the overall
54 operation and maintenance of a birth center or an advanced birth
55 center.

56 ~~(9)(8)~~ "Low-risk pregnancy" means a pregnancy which is
57 expected to result in an uncomplicated birth, as determined
58 through risk criteria developed by rule of the department, and
59 which is accompanied by adequate prenatal care.

60 Section 4. Section 383.305, Florida Statutes, is amended
61 to read:

62 383.305 Licensure; fees.—

63 (1) In accordance with s. 408.805, an applicant for
64 licensure as a birth center or an advanced birth center or a
65 licensee shall pay a fee for each license application submitted

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66 under ss. 383.30-383.335 and part II of chapter 408. The amount
67 of the fee shall be established by rule.

68 (2) Each applicant for licensure and each licensee must
69 comply with the requirements of this chapter and part II of
70 chapter 408.

71 Section 5. Section 383.307, Florida Statutes, is amended
72 to read:

73 383.307 Administration of birth center and advanced birth
74 center.-

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

78 (a) The governing body shall develop and display a table
79 of organization which shows the structure of the birth center or
80 advanced birth center and identifies the governing body, the
81 ~~birth center~~ director, the clinical director, the clinical
82 staff, and the medical consultant.

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

87 (2) There shall be an adequate number of licensed
88 personnel to provide clinical services needed by mothers and
89 newborns and a sufficient number of qualified personnel to

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90 provide services for families and to maintain the birth center
91 or the advanced birth center.

92 (3) All clinical staff members and consultants shall hold
93 current licenses from this state to practice their respective
94 disciplines.

95 (4) Clinical staff members and consultants shall adopt
96 bylaws which are subject to the approval of the governing body
97 and which shall include recommendations for clinical staff or
98 consultation appointments, delineation of clinical privileges,
99 and the organization of the clinical staff.

100 Section 6. Section 383.3081, Florida Statutes, is created
101 to read:

102 383.3081 Advanced birth center facility and equipment;
103 requirements.-

104 (1) An advanced birth center shall meet all of the
105 requirements of s. 383.308, Florida Statutes.

106 (2) An advanced birth center shall be operated and staffed
107 24 hours per day, 7 days per week.

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

111 Section 7. Section 383.309, Florida Statutes, is amended
112 to read:

113 383.309 Minimum standards for birth centers and advanced
114 birth centers; rules and enforcement.-

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

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

122 (b) Infection control, housekeeping, sanitary conditions,
123 disaster plan, and medical record procedures that will
124 adequately protect patient care and provide safety are
125 established and implemented.

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

128 (2) Minimum standards adopted by rule for advanced birth
129 centers must be equivalent to the minimum standards adopted for
130 ambulatory surgical centers pursuant to s. 395.1055, F.S., and
131 shall include sanitary conditions for food handling and food
132 service.

133 ~~(32)~~ The agency may not establish any rule governing the
134 design, construction, erection, alteration, modification,
135 repair, or demolition of birth centers or advanced birth
136 centers. It is the intent of the Legislature to preempt that
137 function to the Florida Building Commission and the State Fire
138 Marshal through adoption and maintenance of the Florida Building
139 Code and the Florida Fire Prevention Code. However, the agency

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140 shall provide technical assistance to the commission and the
141 State Fire Marshal in updating the construction standards of the
142 Florida Building Code and the Florida Fire Prevention Code which
143 govern birth centers and advanced birth centers. In addition,
144 the agency may enforce the special-occupancy provisions of the
145 Florida Building Code and the Florida Fire Prevention Code which
146 apply to birth centers or advanced birth centers in conducting
147 any inspection authorized under this chapter or part II of
148 chapter 408. At a minimum, advanced birth centers must comply
149 with the Florida Building Code and Florida Fire Prevention Code
150 standards for ambulatory surgical centers.

151 Section 8. Section 383.3105, Florida Statutes, is amended
152 to read:

153 383.3105 Patients consenting to adoptions; protocols.—

154 (1) Each licensed birth center and advanced birth center
155 ~~facility~~ shall adopt a protocol that at a minimum provides for
156 birth center and advanced birth center ~~facility~~ staff to be
157 knowledgeable of the waiting periods, revocation and the
158 contents of the consent to adoption as contained in s.
159 63.082(4), and describes the supportive and unbiased manner in
160 which ~~facility~~ staff will interact with birth parents and
161 prospective adoptive parents regarding the adoption, in
162 particular during the waiting period required in s. 63.082(4)(b)
163 before consenting to an adoption.

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164 (2) The protocol shall be in writing and be provided upon
165 request to any birth parent or prospective adoptive parent of a
166 child born in the birth center and advanced birth center
167 ~~facility~~.

168 Section 9. Section 383.311, Florida Statutes, is amended
169 to read:

170 383.311 Education and orientation for birth center and
171 advanced birth center clients and their families.—

172 (1) The clients and their families shall be fully informed
173 of the policies and procedures of the birth center or advanced
174 birth center, including, but not limited to, policies and
175 procedures on:

176 (a) The selection of clients.

177 (b) The expectation of self-help and family/client
178 relationships.

179 (c) The qualifications of the clinical staff.

180 (d) The transfer to secondary or tertiary care.

181 (e) The philosophy of childbirth care and the scope of
182 services.

183 (f) The customary length of stay after delivery.

184 (2) The clients shall be prepared for childbirth and
185 childbearing by education in:

186 (a) The course of pregnancy and normal changes occurring
187 during pregnancy.

188 (b) The need for prenatal care.

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- 189 (c) Nutrition, including encouragement of breastfeeding.
190 (d) The effects of smoking and substance abuse.
191 (e) Labor and delivery.
192 (f) The care of the newborn to include safe sleep
193 practices and the possible causes of Sudden Unexpected Infant
194 Death.

195 Section 10. Section 383.312, Florida Statutes, is amended
196 to read:

197 383.312 Prenatal care of birth center and advanced birth
198 center clients.—

199 (1) A birth center and an advanced birth center shall
200 ensure that their ~~its~~ clients have adequate prenatal care, as
201 defined by the agency, and shall ensure that serological tests
202 are administered as required by this chapter.

203 (2) Records of prenatal care shall be maintained for each
204 client and shall be available during labor and delivery.

205 Section 11. Section 383.313, Florida Statutes, is amended
206 to read:

207 383.313 Birth center performance of laboratory and
208 surgical services; use of anesthetic and chemical agents.—

209 (1) LABORATORY SERVICES.—A birth center may collect
210 specimens for those tests that are requested under protocol. A
211 birth center may perform simple laboratory tests, as defined by
212 rule of the agency, and is exempt from the requirements of
213 chapter 483, provided no more than five physicians are employed

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214 by the birth center and testing is conducted exclusively in
215 connection with the diagnosis and treatment of clients of the
216 birth center.

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

221 (3) ADMINISTRATION OF ANALGESIA AND ANESTHESIA.—General
222 and conduction anesthesia may not be administered at a birth
223 center. Systemic analgesia may be administered, and local
224 anesthesia for pudendal block and episiotomy repair may be
225 performed if procedures are outlined by the clinical staff and
226 performed by personnel with statutory authority to do so.

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

232 Section 12. Section 383.3131, Florida Statutes, is created
233 to read:

234 383.3131 Advanced birth center performance of laboratory
235 and surgical services; use of anesthetic and chemical agents.—

236 (1) LABORATORY SERVICES. An advanced birth center may
237 collect specimens for those tests that are requested under
238 protocol. An advanced birth center may perform laboratory tests,

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239 as defined by rule of the agency. Laboratories located in
240 advanced birth centers must be licensed as a clinical laboratory
241 under chapter 483.

242 (2) SURGICAL SERVICES. In addition to surgical procedures
243 authorized pursuant to s. 383.313(2), surgical procedures are
244 limited to uncomplicated cesarean section deliveries, and
245 surgical management of immediate complications. Postpartum
246 sterilization may be performed prior to discharge of the patient
247 that has given birth during that admission. Circumcisions may be
248 performed prior to discharge of the newborn infant.

249 (3) ADMINISTRATION OF ANALGESIA AND ANESTHESIA.—General,
250 conduction and local anesthesia may be administered at an
251 advanced birth center if administered by personnel with the
252 statutory authority to do so. All general anesthesia shall be
253 administered by an anesthesiologist or a certified registered
254 nurse anesthetist in accordance with s. 464.012. When general
255 anesthesia is administered, a physician or a certified
256 registered nurse anesthetist shall be present in the advanced
257 birthing center during the anesthesia and post-anesthesia
258 recovery period until the patient is fully alert.

259 (4) INTRAPARTAL USE OF CHEMICAL AGENTS.—Labor may be
260 inhibited, stimulated, or augmented with chemical agents during
261 the first or second stage of labor at an advanced birth center
262 if prescribed by personnel with statutory authority to do so.
263 Labor may be electively induced in a patient at thirty-nine

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264 weeks of gestation or greater with a documented Bishop Score of
265 eight or greater.

266 Section 13. Section 383.315, Florida Statutes, is amended
267 to read:

268 383.315 Agreements with consultants for advice or
269 services; maintenance.—

270 (1) A birth center and an advanced birth center shall
271 maintain in writing a consultation agreement, signed within the
272 current license period, with each consultant who has agreed to
273 provide advice and services to the birth center and advanced
274 birth center as requested.

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

277 (3) An advanced birth center shall either employ or
278 maintain an agreement with an obstetrician to be available to
279 attend and available to perform cesarean section deliveries,
280 when necessary.

281 Section 14. Section 383.316, Florida Statutes, is amended
282 to read:

283 383.316 Transfer and transport of clients to hospitals.—

284 (1) If unforeseen complications arise during labor,
285 delivery, or postpartum the client shall be transferred to a
286 hospital.

287 (2) Each licensed birth center or advanced birth center
288 facility shall make arrangements with a local ambulance service

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289 licensed under chapter 401 for the transport of emergency
290 patients to a hospital. Such arrangements shall be documented in
291 the center's policy and procedures manual ~~of the facility~~ if the
292 birth center or advanced birth center does not own or operate a
293 licensed ambulance. The policy and procedures manual shall also
294 contain specific protocols for the transfer of any patient to a
295 licensed hospital.

296 (3) A licensed birth center or advanced birth center
297 ~~facility~~ shall identify neonatal-specific transportation
298 services, including ground and air ambulances; list their
299 particular qualifications; and have the telephone numbers for
300 access to these services clearly listed and immediately
301 available.

302 (4) The birth center or advanced birth center shall assess
303 and document ~~Annual assessments of~~ the transportation services
304 and transfer protocols annually ~~shall be made and documented~~.

305 Section 15. Section 383.318, Florida Statutes, is amended
306 to read:

307 383.318 Postpartum care for birth center and advanced
308 birth center clients and infants.-

309 (1) A mother and her infant shall be dismissed from a ~~the~~
310 birth center within 24 hours after the birth of the infant,
311 except in unusual circumstances as defined by rule of the
312 agency. If a mother or an infant is retained at the birth center
313 for more than 24 hours after the birth, a report shall be filed

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314 with the agency within 48 hours of the birth describing the
315 circumstances and the reasons for the decision.

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

321 (b) If a mother or an infant is retained at the advanced
322 birth center for more than the time frames set forth in
323 paragraph (a), a report shall be filed with the agency within 48
324 hours after the scheduled discharge time describing the
325 circumstances and the reasons for the decision.

326 (3) ~~(2)~~ A prophylactic shall be instilled in the eyes of
327 each newborn in accordance with s. 383.04.

328 (4) ~~(3)~~ Postpartum evaluation and followup care shall be
329 provided, which shall include:

330 (a) Physical examination of the infant.

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

332 (c) Referral to sources for pediatric care.

333 (d) Maternal postpartum assessment.

334 (e) Instruction in child care, including immunization,
335 breastfeeding, safe sleep practices, and possible causes of
336 Sudden Unexpected Infant Death.

337 (f) Family planning services.

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

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339 Section 16. Section 383.324, Florida Statutes, is amended
340 to read:

341 383.324 Inspections and investigations; inspection fees.-
342 Each birth center and advanced birth center ~~facility~~ licensed
343 under s. 383.305 shall pay to the agency an inspection fee
344 established by rule of the agency. In addition to the
345 requirements of part II of chapter 408, the agency shall
346 coordinate all periodic inspections for licensure made by the
347 agency to ensure that the cost to the birth center and advanced
348 birth center ~~facility~~ of such inspections and the disruption of
349 services by such inspections is minimized.

350 Section 17. Section 383.327, Florida Statutes, is amended
351 to read:

352 383.327 Birth and death records; reports.- Each licensed
353 birth center and advanced birth center shall:

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

357 (2) Immediately report each maternal death, newborn death,
358 and stillbirth ~~shall be reported immediately~~ to the medical
359 examiner.

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

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362 (4) Annually submit a report ~~shall be submitted annually~~
363 to the agency. The contents of the report shall be prescribed by
364 rule of the agency.

365 Section 18. Section 383.33, Florida Statutes, is amended
366 to read:

367 383.33 Administrative penalties; moratorium on
368 admissions.—

369 (1) In addition to the requirements of part II of chapter
370 408, the agency may impose an administrative fine not to exceed
371 \$500 per violation per day for the violation of any provision of
372 ss. 383.30-383.335, part II of chapter 408, or applicable rules.

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

376 (a) The severity of the violation, including the
377 probability that death or serious harm to the health or safety
378 of any person will result or has resulted; the severity of the
379 actual or potential harm; and the extent to which the provisions
380 of ss. 383.30-383.335, part II of chapter 408, or applicable
381 rules were violated.

382 (b) Actions taken by the licensee to correct the
383 violations or to remedy complaints.

384 (c) Any previous violations by the licensee.

385 (3) In accordance with part II of chapter 408, the agency
386 may impose an immediate moratorium on elective admissions to any

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387 licensed birth center or advanced birth center ~~facility~~,
388 building or portion thereof, or service when the agency
389 determines that any condition in the center ~~facility~~ presents a
390 threat to the public health or safety.

391 Section 19. Section 383.332, Florida Statutes, is amended
392 to read:

393 383.332 Establishing, managing, or operating a birth
394 center or an advanced birth center without a license; penalty.-
395 Any person who establishes, conducts, manages, or operates any
396 birth center or advanced birth center ~~facility~~ without a license
397 issued under s. 383.305 and part II of chapter 408 commits a
398 misdemeanor and, upon conviction, shall be fined not more than
399 \$100 for the first offense and not more than \$500 for each
400 subsequent offense; and each day of continuing violation after
401 conviction shall be considered a separate offense.

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

404 465.003 Definitions.-As used in this chapter, the term:

405 (11)(a) "Pharmacy" includes a community pharmacy, an
406 institutional pharmacy, a nuclear pharmacy, a special pharmacy,
407 and an Internet pharmacy.

408 1. The term "community pharmacy" includes every location
409 where medicinal drugs are compounded, dispensed, stored, or sold
410 or where prescriptions are filled or dispensed on an outpatient
411 basis.

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412 2. The term "institutional pharmacy" includes every
413 location in a hospital, clinic, advanced birth center, nursing
414 home, dispensary, sanitarium, extended care facility, or other
415 facility, hereinafter referred to as "health care institutions,"
416 where medicinal drugs are compounded, dispensed, stored, or
417 sold.

418 3. The term "nuclear pharmacy" includes every location
419 where radioactive drugs and chemicals within the classification
420 of medicinal drugs are compounded, dispensed, stored, or sold.
421 The term "nuclear pharmacy" does not include hospitals licensed
422 under chapter 395 or the nuclear medicine facilities of such
423 hospitals.

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

427 5. The term "Internet pharmacy" includes locations not
428 otherwise licensed or issued a permit under this chapter, within
429 or outside this state, which use the Internet to communicate
430 with or obtain information from consumers in this state and use
431 such communication or information to fill or refill
432 prescriptions or to dispense, distribute, or otherwise engage in
433 the practice of pharmacy in this state. Any act described in
434 this definition constitutes the practice of pharmacy as defined
435 in subsection (13).

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436 (b) The pharmacy department of any permittee shall be
437 considered closed whenever a Florida licensed pharmacist is not
438 present and on duty. The term "not present and on duty" shall
439 not be construed to prevent a pharmacist from exiting the
440 prescription department for the purposes of consulting or
441 responding to inquiries or providing assistance to patients or
442 customers, attending to personal hygiene needs, or performing
443 any other function for which the pharmacist is responsible,
444 provided that such activities are conducted in a manner
445 consistent with the pharmacist's responsibility to provide
446 pharmacy services.

447 Section 21. Paragraph (c) of subsection (2) of section
448 465.019, Florida Statutes, is amended to read:

449 465.019 Institutional pharmacies; permits.—

450 (2) The following classes of institutional pharmacies are
451 established:

452 (c) "Modified Class II institutional pharmacies" are those
453 institutional pharmacies in short-term, primary care treatment
454 centers and advanced birth centers, that meet all the
455 requirements for a Class II permit, except space and equipment
456 requirements.

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

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460

T I T L E A M E N D M E N T

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 1099 (2018)

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461 Remove lines 14-36 and insert:
462 amending s. 383.309, F.S.; providing minimum standards for
463 advanced birth centers; authorizing the Agency for Health Care
464 Administration to enforce specified provisions of the Florida
465 Building Code and the Florida Fire Prevention Code; amending s.
466 383.3105, F.S.; providing applicability of adoption protocols
467 for staff of an advanced birth center; amending s. 383.311,
468 F.S.; providing for the education and orientation of advanced
469 birth center clients and their families; amending s. 383.312,
470 F.S.; providing for an advanced birth center to offer prenatal
471 care; amending s. 383.313, F.S.; providing for laboratory and
472 surgical services at a birth center; s. 383.3131, F.S.;
473 providing requirements for laboratory and surgical services at
474 an advanced birth center; providing conditions for
475 administration of anesthesia; authorizing the intrapartal use of
476 chemical agents; amending s. 383.315, F.S.; requiring an
477 advanced birth center to employ or maintain an agreement with an
478 obstetrician under certain circumstances;

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