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 advanced birth center facilities and equipment; 13 14 amending s. 383.309, F.S.; requiring certain staffing ratios; specifying credentials required of personnel 15 attending patients; authorizing the Agency for Health 16 17 Care Administration to enforce specified provisions of the Florida Building Code and the Florida Fire 18 19 Prevention Code; amending s. 383.31, F.S.; providing criteria for admission of patients; requiring informed 20 21 consent; amending s. 383.3105, F.S.; providing applicability of adoption protocols for staff of an 22 23 advanced birth center; amending s. 383.311, F.S.; providing for the education and orientation of 24 25 advanced birth center clients and their families;

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26 amending s. 383.312, F.S.; providing for an advanced 27 birth center to offer prenatal care; amending s. 28 383.313, F.S.; providing for laboratory and surgical 29 services at a birth center; s. 383.3131, F.S.; 30 providing requirements for laboratory and surgical 31 services at an advanced birth center; providing 32 conditions for administration of anesthesia; authorizing the intrapartal use of chemical agents; 33 amending s. 383.315, F.S.; requiring an advanced birth 34 35 center to employ or maintain an agreement with an 36 obstetric provider under certain circumstances; 37 amending s. 383.316, F.S.; requiring an advanced birth center to provide for transport of emergency patients 38 39 to a hospital; amending s. 383.318, F.S.; providing protocols for postpartum care of clients and infants; 40 providing requirements for followup care; amending s. 41 42 383.324, F.S.; requiring an advanced birth center to 43 pay an inspection fee to the agency; amending s. 383.327, F.S.; requiring an advanced birth center to 44 provide reports of all births and deaths occurring at 45 the center; requiring reports to the agency; amending 46 47 s. 383.33, F.S.; providing for fines, administrative 48 penalties, and moratoriums; amending s. 383.332, F.S.; providing a criminal penalty for operating an 49 50 unlicensed advanced birth center; amending s. 465.003,

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| 51 | F.S.; revising the definition of the term | | | | |
|----|--|--|--|--|--|
| 52 | "institutional pharmacy" to include pharmacies located | | | | |
| 53 | in advanced birth centers; amending s. 465.019, F.S.; | | | | |
| 54 | revising the definition of the term "modified Class II | | | | |
| 55 | institutional pharmacies" to include pharmacies | | | | |
| 56 | located in advanced birth centers; providing an | | | | |
| 57 | effective date. | | | | |
| 58 | | | | | |
| 59 | Be It Enacted by the Legislature of the State of Florida: | | | | |
| 60 | | | | | |
| 61 | Section 1. Section 383.30, Florida Statutes, is amended to | | | | |
| 62 | 2 read: | | | | |
| 63 | 383.30 Birth Center and Advanced Birth Center Licensure | | | | |
| 64 | Act; short titleSections 383.30-383.335 shall be known and may | | | | |
| 65 | be cited as the "Birth Center and Advanced Birth Center | | | | |
| 66 | Licensure Act." | | | | |
| 67 | Section 2. Section 383.301, Florida Statutes, is amended | | | | |
| 68 | to read: | | | | |
| 69 | 383.301 Licensure and regulation of birth centers; | | | | |
| 70 | legislative intentIt is the intent of the Legislature to | | | | |
| 71 | provide for the protection of public health and safety in the | | | | |
| 72 | establishment, maintenance, and operation of birth centers and | | | | |
| 73 | advanced birth centers by providing for licensure of birth | | | | |
| 74 | centers and advanced birth centers and for the development, | | | | |
| 75 | establishment, and enforcement of minimum standards with respect | | | | |
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76 to birth centers and advanced birth centers. The requirements of 77 part II of chapter 408 shall apply to the provision of services 78 that require licensure pursuant to ss. 383.30-383.335 and part 79 II of chapter 408 and to entities licensed by or applying for 80 such licensure from the Agency for Health Care Administration pursuant to ss. 383.30-383.335. A license issued by the agency 81 82 is required in order to operate a birth center or an advanced 83 birth center in this state. Section 3. Subsections (1) through (10) of section 84 85 383.302, Florida Statutes, are renumbered as subsections (2) through (11), respectively, present subsections (3), (4), (5), 86 87 and (8) are amended, and a new subsection (1) is added to that 88 section, to read: 89 383.302 Definitions of terms used in ss. 383.30-383.335.-90 As used in ss. 383.30-383.335, the term: (1) "Advanced birth center" means a birth center that is 91 92 authorized and equipped to accept patients who plan to have a 93 vaginal delivery of a fetus with a gestational age of 37 through 94 41 weeks or who have had or plan to have a caesarean delivery. 95 (4) (3) "Clinical staff" means individuals employed full 96 time or part time by a birth center or an advanced birth center 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 99 100 services to a birth center or an advanced birth center and who Page 4 of 22

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| 101 | either: | | | | | |
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| 102 | (a) Is certified or eligible for certification by the | | | | | |
| 103 | American Board of Obstetrics and Gynecology, or | | | | | |
| 104 | (b) Has hospital obstetrical privileges. | | | | | |
| 105 | (6)(5) "Governing body" means any individual, group, | | | | | |
| 106 | corporation, or institution which is responsible for the overall | | | | | |
| 107 | operation and maintenance of a birth center or an advanced birth | | | | | |
| 108 | center. | | | | | |
| 109 | <u>(9)</u> "Low-risk pregnancy" means a pregnancy which is | | | | | |
| 110 | expected to result in an uncomplicated birth, as determined | | | | | |
| 111 | through risk criteria developed by rule of the department, and | | | | | |
| 112 | which is accompanied by adequate prenatal care, as defined by | | | | | |
| 113 | the agency. | | | | | |
| 114 | Section 4. Section 383.305, Florida Statutes, is amended | | | | | |
| 115 | to read: | | | | | |
| 116 | 383.305 Licensure; fees | | | | | |
| 117 | (1) In accordance with s. 408.805, an applicant <u>for</u> | | | | | |
| 118 | licensure as a birth center or an advanced birth center or a | | | | | |
| 119 | licensee shall pay a fee for each license application submitted | | | | | |
| 120 | under ss. 383.30-383.335 and part II of chapter 408. The amount | | | | | |
| 121 | of the fee shall be established by rule. | | | | | |
| 122 | (2) Each applicant for licensure and each licensee must | | | | | |
| 123 | comply with the requirements of this chapter and part II of | | | | | |
| 124 | chapter 408. | | | | | |
| 125 | Section 5. Section 383.307, Florida Statutes, is amended | | | | | |
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126 to read:

127 383.307 Administration of birth center <u>and advanced birth</u> 128 <u>center.-</u>

(1) Each birth center <u>and advanced birth center</u> shall have
a governing body which is responsible for the overall operation
and maintenance of the birth center.

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

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

141 (2) There shall be an adequate number of licensed 142 personnel to provide clinical services needed by mothers and 143 newborns and a sufficient number of qualified personnel to 144 provide services for families and to maintain the birth center 145 or the advanced birth center.

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

(4) Clinical staff members and consultants shall adoptbylaws which are subject to the approval of the governing body

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| 1 - 1 | | | | | |
|-------|--|--|--|--|--|
| 151 | and which shall include recommendations for clinical staff or | | | | |
| 152 | consultation appointments, delineation of clinical privileges, | | | | |
| 153 | and the organization of the clinical staff. | | | | |
| 154 | Section 6. Section 383.3081, Florida Statutes, is created | | | | |
| 155 | to read: | | | | |
| 156 | 383.3081 Advanced birth center facility and equipment; | | | | |
| 157 | requirements | | | | |
| 158 | (1) An advanced birth center shall meet all of the | | | | |
| 159 | requirements of s. 383.308. | | | | |
| 160 | (2) An advanced birth center shall be operated and staffed | | | | |
| 161 | 24 hours per day, 7 days per week. | | | | |
| 162 | (3) Each advanced birth center shall have at least one | | | | |
| 163 | properly equipped, dedicated surgical suite for the performance | | | | |
| 164 | of cesarean deliveries. | | | | |
| 165 | (4) Food service shall be provided directly by the | | | | |
| 166 | advanced birth center or through a contract with a third-party | | | | |
| 167 | vendor and shall be provided pursuant to rules adopted under | | | | |
| 168 | chapter 381. | | | | |
| 169 | Section 7. Section 383.309, Florida Statutes, is amended | | | | |
| 170 | to read: | | | | |
| 171 | 383.309 Minimum standards for birth centers and advanced | | | | |
| 172 | birth centers; rules and enforcement | | | | |
| 173 | (1) The agency shall adopt and enforce rules to administer | | | | |
| 174 | ss. 383.30-383.335 and part II of chapter 408, which rules shall | | | | |
| 175 | include, but are not limited to, reasonable and fair minimum | | | | |
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| | Page 7 of 22 | | | | |

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176 standards for ensuring that:

177 Sufficient numbers and qualified types of personnel (a) 178 and occupational disciplines are available at all times to 179 provide necessary and adequate patient care and safety. An advanced birth center must have at least one registered nurse or 180 181 advanced registered nurse practitioner present in the facility 182 for every two patients in labor and at least one registered 183 nurse or advanced registered nurse practitioner present in the 184 facility for every four newborn infants.

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

(c) Licensed facilities are established, organized, andoperated consistent with established programmatic standards.

191 (2)The agency may not establish any rule governing the 192 design, construction, erection, alteration, modification, 193 repair, or demolition of birth centers or advanced birth 194 centers. It is the intent of the Legislature to preempt that 195 function to the Florida Building Commission and the State Fire 196 Marshal through adoption and maintenance of the Florida Building 197 Code and the Florida Fire Prevention Code. However, the agency shall provide technical assistance to the commission and the 198 State Fire Marshal in updating the construction standards of the 199 200 Florida Building Code and the Florida Fire Prevention Code which

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201 govern birth centers and advanced birth centers. In addition, 202 the agency may enforce the special-occupancy provisions of the 203 Florida Building Code and the Florida Fire Prevention Code which 204 apply to birth centers or advanced birth centers in conducting 205 any inspection authorized under this chapter or part II of 206 chapter 408. However, a delivery or surgical suite in an 207 advanced birth center shall meet the same design and 208 construction standards applicable to similar suites in 209 ambulatory surgical centers licensed under chapter 395 and the 210 agency may enforce such standards. 211 Section 8. Section 383.31, Florida Statutes, is amended to 212 read: 213 383.31 Selection of clients; informed consent.-214 (1) (a) A birth center may accept only those patients who 215 are expected to have normal pregnancies, labors, and deliveries. The criteria for the selection of clients and the 216 (b) 217 establishment of risk status shall be defined by rule of the 218 agency. 219 (2) An advanced birth center may accept any patient who 220 meets the criteria of subsection (1) and also may accept a 221 patient who has: 222 Been screened and qualifies for trial of labor after (a) cesarean delivery. 223 (b) A planned low-risk cesarean delivery. 224 225 (c) An anticipated vaginal delivery of a fetus with a

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226 gestational age of 37 through 41 weeks. 227 A patient may not be accepted for care until the (3)(2)(a) 228 patient has signed a client informed-consent form. 229 (b) The agency shall develop a client informed-consent 230 form to be used by the center to inform the client of the 231 benefits and risks related to childbirth outside a hospital. 232 Section 9. Section 383.3105, Florida Statutes, is amended 233 to read: 234 383.3105 Patients consenting to adoptions; protocols.-235 Each licensed birth center and advanced birth center (1)facility shall adopt a protocol that at a minimum provides for 236 237 birth center and advanced birth center facility staff to be 238 knowledgeable of the waiting periods, revocation and the 239 contents of the consent to adoption as contained in s. 240 63.082(4), and describes the supportive and unbiased manner in 241 which facility staff will interact with birth parents and 242 prospective adoptive parents regarding the adoption, in 243 particular during the waiting period required in s. 63.082(4)(b) 244 before consenting to an adoption. 245 The protocol shall be in writing and be provided upon (2) 246 request to any birth parent or prospective adoptive parent of a 247 child born in the birth center and advanced birth center 248 facility. Section 10. Section 383.311, Florida Statutes, is amended 249 to read: 250

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251 383.311 Education and orientation for birth center and 252 advanced birth center clients and their families.-253 (1)The clients and their families shall be fully informed 254 of the policies and procedures of the birth center or advanced 255 birth center, including, but not limited to, policies and 256 procedures on: The selection of clients. 257 (a) 258 (b) The expectation of self-help and family/client 259 relationships. 260 (C) The qualifications of the clinical staff. 261 (d) The transfer to secondary or tertiary care. 262 (e) The philosophy of childbirth care and the scope of 263 services. 264 (f) The customary length of stay after delivery. 265 (2) The clients shall be prepared for childbirth and 266 childbearing by education in: 267 (a) The course of pregnancy and normal changes occurring 268 during pregnancy. 269 (b) The need for prenatal care. 270 Nutrition, including encouragement of breastfeeding. (C) 271 (d) The effects of smoking and substance abuse. 272 Labor and delivery. (e) The care of the newborn to include safe sleep 273 (f) 274 practices and the possible causes of Sudden Unexpected Infant Death. 275

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276 Section 11. Section 383.312, Florida Statutes, is amended 277 to read:

278 383.312 Prenatal care of birth center <u>and advanced birth</u> 279 center clients.-

(1) A birth center <u>and an advanced birth center</u> shall
ensure that <u>their</u> its clients have adequate prenatal care, as
defined by the agency, and shall ensure that serological tests
are administered as required by this chapter.

(2) Records of prenatal care shall be maintained for eachclient and shall be available during labor and delivery.

286 Section 12. Section 383.313, Florida Statutes, is amended 287 to read:

288383.313Birth center performance of laboratory and289surgical services; use of anesthetic and chemical agents.-

290 LABORATORY SERVICES.-A birth center may collect (1)291 specimens for those tests that are requested under protocol. A 292 birth center may perform simple laboratory tests, as defined by 293 rule of the agency, and is exempt from the requirements of 294 chapter 483, provided no more than five physicians are employed 295 by the birth center and testing is conducted exclusively in 296 connection with the diagnosis and treatment of clients of the 297 birth center.

(2) SURGICAL SERVICES.—Surgical procedures shall be
 limited to those normally performed during uncomplicated
 childbirths, such as episiotomies and repairs and may shall not

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| 301 | include operative obstetrics or caesarean sections. | | | | | |
|-----|--|--|--|--|--|--|
| 302 | (3) ADMINISTRATION OF ANALGESIA AND ANESTHESIAGeneral | | | | | |
| 303 | and conduction anesthesia may not be administered at a birth | | | | | |
| 304 | center. Systemic analgesia may be administered, and local | | | | | |
| 305 | anesthesia for pudendal block and episiotomy repair may be | | | | | |
| 306 | performed if procedures are outlined by the clinical staff and | | | | | |
| 307 | performed by personnel with statutory authority to do so. | | | | | |
| 308 | (4) INTRAPARTAL USE OF CHEMICAL AGENTSLabor may not be | | | | | |
| 309 | inhibited, stimulated, or augmented with chemical agents during | | | | | |
| 310 | the first or second stage of labor unless prescribed by | | | | | |
| 311 | personnel with statutory authority to do so and unless in | | | | | |
| 312 | connection with and prior to emergency transport. | | | | | |
| 313 | Section 13. Section 383.3131, Florida Statutes, is created | | | | | |
| 314 | to read: | | | | | |
| 315 | 383.3131 Advanced birth center performance of laboratory | | | | | |
| 316 | and surgical services; use of anesthetic and chemical agents | | | | | |
| 317 | (1) LABORATORY SERVICES.—A laboratory located in an | | | | | |
| 318 | advanced birth center is subject to the requirements of chapter | | | | | |
| 319 | 483. | | | | | |
| 320 | (2) SURGICAL SERVICESSurgical procedures shall be | | | | | |
| 321 | limited to uncomplicated cesarean deliveries, surgical | | | | | |
| 322 | management of immediate complications, and procedures normally | | | | | |
| 323 | performed during uncomplicated childbirths, such as episiotomies | | | | | |
| 324 | and repairs of vaginal lacerations. Postpartum sterilization may | | | | | |
| 325 | be performed on a patient who has given birth in the advanced | | | | | |
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| 326 | birth center with the consent of the patient. A newborn infant | | | | |
|-----|--|--|--|--|--|
| 327 | may be circumcised before discharge with the consent of the | | | | |
| 328 | | | | | |
| 329 | (3) ADMINISTRATION OF ANESTHESIAGeneral, conduction, and | | | | |
| 330 | local anesthesia may be administered at an advanced birth center | | | | |
| 331 | if such services are provided in accordance with established | | | | |
| 332 | protocol required by state law. All general anesthesia shall be | | | | |
| 333 | | | | | |
| 334 | nurse anesthetist. When general anesthesia is administered, a | | | | |
| 335 | physician or a certified registered nurse anesthetist shall be | | | | |
| 336 | present in the advanced birthing center during the anesthesia | | | | |
| 337 | and postanesthesia recovery period until the patient is fully | | | | |
| 338 | alert. When anesthesia services are performed by a certified | | | | |
| 339 | registered nurse anesthetist, a board-certified anesthesiologist | | | | |
| 340 | shall be on call and available at all times. | | | | |
| 341 | (4) INTRAPARTAL USE OF CHEMICAL AGENTSLabor may be | | | | |
| 342 | inhibited, stimulated, or augmented with chemical agents during | | | | |
| 343 | the first or second stage of labor at an advanced birth center | | | | |
| 344 | if prescribed by personnel with statutory authority to do so. | | | | |
| 345 | Labor may be electively induced at 39 weeks' gestation or later | | | | |
| 346 | for a patient with a documented Bishop score of 8 or greater. | | | | |
| 347 | Section 14. Section 383.315, Florida Statutes, is amended | | | | |
| 348 | to read: | | | | |
| 349 | 383.315 Agreements with consultants for advice or | | | | |
| 350 | services; maintenance | | | | |
| | | | | | |

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| 351 | (1) A birth center and an advanced birth center shall | | | | |
|-----|--|--|--|--|--|
| 352 | maintain in writing a consultation agreement, signed within the | | | | |
| 353 | current license period, with each consultant who has agreed to | | | | |
| 354 | provide advice and services to the birth center and advanced | | | | |
| 355 | <u>birth center</u> as requested. | | | | |
| 356 | (2) Consultation may be provided onsite or by telephone, | | | | |
| 357 | as required by clinical and geographic conditions. | | | | |
| 358 | (3) An advanced birth center shall either employ or | | | | |
| 359 | maintain an agreement with an obstetric provider with privileges | | | | |
| 360 | to perform and who is available to attend all cesarean | | | | |
| 361 | deliveries. | | | | |
| 362 | Section 15. Section 383.316, Florida Statutes, is amended | | | | |
| 363 | to read: | | | | |
| 364 | 383.316 Transfer and transport of clients to hospitals | | | | |
| 365 | (1) If unforeseen complications arise during labor, | | | | |
| 366 | delivery, or postpartum the client shall be transferred to a | | | | |
| 367 | hospital. | | | | |
| 368 | (2) Each licensed <u>birth center or advanced birth center</u> | | | | |
| 369 | facility shall make arrangements with a local ambulance service | | | | |
| 370 | licensed under chapter 401 for the transport of emergency | | | | |
| 371 | patients to a hospital. Such arrangements shall be documented in | | | | |
| 372 | the policy and procedures <u>center's</u> manual of the facility if the | | | | |
| 373 | birth center <u>or advanced birth center</u> does not own or operate a | | | | |
| 374 | licensed ambulance. The policy and procedures manual shall also | | | | |
| 375 | contain specific protocols for the transfer of any patient to a | | | | |
| | Dage 15 of 22 | | | | |
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376 licensed hospital. 377 A licensed birth center or advanced birth center (3) 378 facility shall identify neonatal-specific transportation 379 services, including ground and air ambulances; list their 380 particular qualifications; and have the telephone numbers for 381 access to these services clearly listed and immediately 382 available. 383 (4) The birth center or advanced birth center shall assess and document Annual assessments of the transportation services 384 385 and transfer protocols annually shall be made and documented. Section 16. Section 383.318, Florida Statutes, is amended 386 387 to read: 388 383.318 Postpartum care for birth center and advanced 389 birth center clients and infants.-390 A mother and her infant shall be dismissed from a the (1)391 birth center within 24 hours after the birth of the infant, 392 except in unusual circumstances as defined by rule of the 393 agency. If a mother or an infant is retained at the birth center 394 for more than 24 hours after the birth, a report shall be filed 395 with the agency within 48 hours of the birth describing the 396 circumstances and the reasons for the decision. 397 (2) (a) A mother and her infant shall be discharged from an advanced birth center within 48 hours after the birth of the 398 infant for a vaginal delivery and within 72 hours when delivery 399 is by cesarean section, except in unusual circumstances defined 400

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| 401 | by rule of the agency. | | | | | |
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| 402 | (b) If a mother or an infant is retained at the advanced | | | | | |
| 403 | birth center for more than the time frames set forth in | | | | | |
| 404 | paragraph (a), a report shall be filed with the agency within 48 | | | | | |
| 405 | hours after the scheduled discharge time describing the | | | | | |
| 406 | circumstances and the reasons for the decision. | | | | | |
| 407 | (3) (2) A prophylactic shall be instilled in the eyes of | | | | | |
| 408 | each newborn in accordance with s. 383.04. | | | | | |
| 409 | (4) (3) Postpartum evaluation and followup care shall be | | | | | |
| 410 | provided, which shall include: | | | | | |
| 411 | (a) Physical examination of the infant. | | | | | |
| 412 | (b) Metabolic screening tests required by s. 383.14. | | | | | |
| 413 | (c) Referral to sources for pediatric care. | | | | | |
| 414 | (d) Maternal postpartum assessment. | | | | | |
| 415 | (e) Instruction in child care, including immunization, | | | | | |
| 416 | breastfeeding, safe sleep practices, and possible causes of | | | | | |
| 417 | Sudden Unexpected Infant Death. | | | | | |
| 418 | (f) Family planning services. | | | | | |
| 419 | (g) Referral to secondary or tertiary care, as indicated. | | | | | |
| 420 | Section 17. Section 383.324, Florida Statutes, is amended | | | | | |
| 421 | to read: | | | | | |
| 422 | 383.324 Inspections and investigations; inspection fees | | | | | |
| 423 | Each <u>birth center and advanced birth center</u> facility licensed | | | | | |
| 424 | under s. 383.305 shall pay to the agency an inspection fee | | | | | |
| 425 | established by rule of the agency. In addition to the | | | | | |
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| 426 | requirements of part II of chapter 408, the agency shall | | | | | |
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| 427 | coordinate all periodic inspections for licensure made by the | | | | | |
| 428 | agency to ensure that the cost to the birth center and advanced | | | | | |
| 429 | birth center facility of such inspections and the disruption of | | | | | |
| 430 | services by such inspections is minimized. | | | | | |
| 431 | Section 18. Section 383.327, Florida Statutes, is amended | | | | | |
| 432 | to read: | | | | | |
| 433 | 383.327 Birth and death records; reportsEach licensed | | | | | |
| 434 | birth center and advanced birth center shall: | | | | | |
| 435 | (1) <u>File</u> a completed certificate of birth shall be filed | | | | | |
| 436 | with the local registrar within 5 days of each birth in | | | | | |
| 437 | accordance with chapter 382. | | | | | |
| 438 | (2) Immediately report each maternal death, newborn death, | | | | | |
| 439 | and stillbirth shall be reported immediately to the medical | | | | | |
| 440 | examiner. | | | | | |
| 441 | (3) The licensee shall Comply with all requirements of | | | | | |
| 442 | this chapter and rules promulgated hereunder. | | | | | |
| 443 | (4) Annually submit a report shall be submitted annually | | | | | |
| 444 | to the agency. The contents of the report shall be prescribed by | | | | | |
| 445 | rule of the agency. | | | | | |
| 446 | Section 19. Section 383.33, Florida Statutes, is amended | | | | | |
| 447 | to read: | | | | | |
| 448 | 383.33 Administrative penalties; moratorium on | | | | | |
| 449 | admissions | | | | | |
| 450 | (1) In addition to the requirements of part II of chapter | | | | | |
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408, the agency may impose an administrative fine not to exceed 451 452 \$500 per violation per day for the violation of any provision of 453 ss. 383.30-383.335, part II of chapter 408, or applicable rules. 454 In determining the amount of the fine to be levied for (2) 455 a violation, as provided in this section, the following factors 456 shall be considered: 457 (a) The severity of the violation, including the 458 probability that death or serious harm to the health or safety 459 of any person will result or has resulted; the severity of the 460 actual or potential harm; and the extent to which the provisions of ss. 383.30-383.335, part II of chapter 408, or applicable 461 462 rules were violated. (b) Actions taken by the licensee to correct the 463 464 violations or to remedy complaints. 465 Any previous violations by the licensee. (C) 466 In accordance with part II of chapter 408, the agency (3) 467 may impose an immediate moratorium on elective admissions to any 468 licensed birth center or advanced birth center facility, 469 building or portion thereof, or service when the agency 470 determines that any condition in the center facility presents a 471 threat to the public health or safety. 472 Section 20. Section 383.332, Florida Statutes, is amended to read: 473 474 383.332 Establishing, managing, or operating a birth center or an advanced birth center without a license; penalty.-475 Page 19 of 22

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Any person who establishes, conducts, manages, or operates any birth center <u>or advanced birth center</u> facility without a license issued under s. 383.305 and part II of chapter 408 commits a misdemeanor and, upon conviction, shall be fined not more than \$100 for the first offense and not more than \$500 for each subsequent offense; and each day of continuing violation after conviction shall be considered a separate offense.

483 Section 21. Subsection (11) of section 465.003, Florida 484 Statutes, is amended to read:

485

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

486 (11)(a) "Pharmacy" includes a community pharmacy, an
487 institutional pharmacy, a nuclear pharmacy, a special pharmacy,
488 and an Internet pharmacy.

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

493 2. The term "institutional pharmacy" includes every 494 location in a hospital, clinic, <u>advanced birth center</u>, nursing 495 home, dispensary, sanitarium, extended care facility, or other 496 facility, hereinafter referred to as "health care institutions," 497 where medicinal drugs are compounded, dispensed, stored, or 498 sold.

3. The term "nuclear pharmacy" includes every locationwhere radioactive drugs and chemicals within the classification

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501 of medicinal drugs are compounded, dispensed, stored, or sold. 502 The term "nuclear pharmacy" does not include hospitals licensed 503 under chapter 395 or the nuclear medicine facilities of such 504 hospitals.

505 4. The term "special pharmacy" includes every location 506 where medicinal drugs are compounded, dispensed, stored, or sold 507 if such locations are not otherwise defined in this subsection.

The term "Internet pharmacy" includes locations not 508 5. otherwise licensed or issued a permit under this chapter, within 509 or outside this state, which use the Internet to communicate 510 with or obtain information from consumers in this state and use 511 512 such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in 513 514 the practice of pharmacy in this state. Any act described in 515 this definition constitutes the practice of pharmacy as defined in subsection (13). 516

517 (b) The pharmacy department of any permittee shall be 518 considered closed whenever a Florida licensed pharmacist is not 519 present and on duty. The term "not present and on duty" shall 520 not be construed to prevent a pharmacist from exiting the 521 prescription department for the purposes of consulting or 522 responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing 523 524 any other function for which the pharmacist is responsible, 525 provided that such activities are conducted in a manner

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526 consistent with the pharmacist's responsibility to provide 527 pharmacy services. 528 Section 22. Paragraph (c) of subsection (2) of section 465.019, Florida Statutes, is amended to read: 529 530 465.019 Institutional pharmacies; permits.-The following classes of institutional pharmacies are 531 (2) established: 532 (c) "Modified Class II institutional pharmacies" are those 533 534 institutional pharmacies in short-term, primary care treatment 535 centers, including advanced birth centers, that meet all the 536 requirements for a Class II permit, except space and equipment 537 requirements. 538 Section 23. This act shall take effect July 1, 2018.

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