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A bill to be entitled An act relating to advanced birth centers; amending s. 383.30, F.S.; revising the short title; amending s. 383.301, F.S.; providing applicability of licensure requirements under pt. II of ch. 408, F.S., to advanced birth centers; amending s. 383.302, F.S.; defining the term "advanced birth center"; revising definitions; amending s. 383.305, F.S.; providing applicability of licensure fee requirements to advanced birth centers; amending s. 383.307, F.S.; providing for administration of advance birth centers; creating s. 383.3081, F.S.; providing requirements for advanced birth center facilities and equipment; amending s. 383.309, F.S.; requiring certain staffing ratios; specifying credentials required of personnel attending patients; authorizing the Agency for Health Care Administration to enforce specified provisions of the Florida Building Code and the Florida Fire Prevention Code; amending s. 383.31, F.S.; providing criteria for admission of patients; requiring informed consent; amending s. 383.3105, F.S.; providing applicability of adoption protocols for staff of an advanced birth center; amending s. 383.311, F.S.; providing for the education and orientation of advanced birth center clients and their families;

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amending s. 383.312, F.S.; providing for an advanced birth center to offer prenatal care; amending s. 383.313, F.S.; providing for laboratory and surgical services at a birth center; s. 383.3131, F.S.; providing requirements for laboratory and surgical services at an advanced birth center; providing conditions for administration of anesthesia; authorizing the intrapartal use of chemical agents; amending s. 383.315, F.S.; requiring an advanced birth center to employ or maintain an agreement with an obstetric provider under certain circumstances; amending s. 383.316, F.S.; requiring an advanced birth center to provide for transport of emergency patients to a hospital; amending s. 383.318, F.S.; providing protocols for postpartum care of clients and infants; providing requirements for followup care; amending s. 383.324, F.S.; requiring an advanced birth center to pay an inspection fee to the agency; amending s. 383.327, F.S.; requiring an advanced birth center to provide reports of all births and deaths occurring at the center; requiring reports to the agency; amending s. 383.33, F.S.; providing for fines, administrative penalties, and moratoriums; amending s. 383.332, F.S.; providing a criminal penalty for operating an unlicensed advanced birth center; amending s. 465.003,

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F.S.; revising the definition of the term "institutional pharmacy" to include pharmacies located in advanced birth centers; amending s. 465.019, F.S.; revising the definition of the term "modified Class II institutional pharmacies" to include pharmacies located in advanced birth centers; providing an effective date.

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

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

383.30 Birth Center <u>and Advanced Birth Center</u> Licensure
Act; short title.—Sections 383.30-383.335 shall be known and may
be cited as the "Birth Center <u>and Advanced Birth Center</u>
Licensure Act."

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

383.301 Licensure and regulation of birth centers; legislative intent.—It is the intent of the Legislature to provide for the protection of public health and safety in the establishment, maintenance, and operation of birth centers and advanced birth centers by providing for licensure of birth centers and advanced birth centers and for the development, establishment, and enforcement of minimum standards with respect

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to birth centers <u>and advanced birth centers</u>. The requirements of part II of chapter 408 shall apply to the provision of services that require licensure pursuant to ss. 383.30-383.335 and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 383.30-383.335. A license issued by the agency is required in order to operate a birth center <u>or an advanced</u> birth center in this state.

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

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

- (1) "Advanced birth center" means a birth center that is authorized and equipped to accept patients who plan to have a vaginal delivery of a fetus with a gestational age of 37 through 41 weeks or who have had or plan to have a caesarean delivery.
- $\underline{(4)}$ "Clinical staff" means individuals employed full time or part time by a birth center or an advanced birth center who are licensed or certified to provide care at childbirth.
- (5)(4) "Consultant" means a physician licensed pursuant to chapter 458 or chapter 459 who agrees to provide advice and services to a birth center or an advanced birth center and who

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101 either:

- (a) Is certified or eligible for certification by the American Board of Obstetrics and Gynecology, or
 - (b) Has hospital obstetrical privileges.
- $\underline{(6)}$ "Governing body" means any individual, group, corporation, or institution which is responsible for the overall operation and maintenance of a birth center or an advanced birth center.
- (9) (8) "Low-risk pregnancy" means a pregnancy which is expected to result in an uncomplicated birth, as determined through risk criteria developed by rule of the department, and which is accompanied by adequate prenatal care, as defined by the agency.
- Section 4. Section 383.305, Florida Statutes, is amended to read:
 - 383.305 Licensure; fees.-
- (1) In accordance with s. 408.805, an applicant <u>for</u>

 <u>licensure as a birth center or an advanced birth center</u> or a

 licensee shall pay a fee for each license application submitted
 under ss. 383.30-383.335 and part II of chapter 408. The amount
 of the fee shall be established by rule.
- (2) Each applicant for licensure and each licensee must comply with the requirements of this chapter and part II of chapter 408.
 - Section 5. Section 383.307, Florida Statutes, is amended

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126 to read:

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383.307 Administration of birth center <u>and advanced birth</u> center.—

- (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.
- (2) There shall be an adequate number of licensed personnel to provide clinical services needed by mothers and newborns and a sufficient number of qualified personnel to provide services for families and to maintain the birth center 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 adopt bylaws which are subject to the approval of the governing body

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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	<pre>birth centers; rules and enforcement</pre>							
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							

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include, but are not limited to, reasonable and fair minimum

standards for ensuring that:

- (a) Sufficient numbers and qualified types of personnel and occupational disciplines are available at all times to provide necessary and adequate patient care and safety. An advanced birth center must have at least one registered nurse or advanced registered nurse practitioner present in the facility for every two patients in labor and at least one registered nurse or advanced registered nurse practitioner present in the 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, and operated consistent with established programmatic standards.
- design, construction, erection, alteration, modification, repair, or demolition of birth centers or advanced birth centers. It is the intent of the Legislature to preempt that function to the Florida Building Commission and the State Fire Marshal through adoption and maintenance of the Florida Building Code and the Florida Fire Prevention Code. However, the agency shall provide technical assistance to the commission and the State Fire Marshal in updating the construction standards of the Florida Building Code and the Florida Fire Prevention Code which

govern birth centers and advanced birth centers. In addition, the agency may enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code which apply to birth centers or advanced birth centers in conducting any inspection authorized under this chapter or part II of chapter 408. However, a delivery or surgical suite in an advanced birth center shall meet the same design and construction standards applicable to similar suites in ambulatory surgical centers licensed under chapter 395 and the agency may enforce such standards.

Section 8. Section 383.31, Florida Statutes, is amended to read:

- 383.31 Selection of clients; informed consent.-
- (1) (a) A birth center may accept only those patients who are expected to have normal pregnancies, labors, and deliveries.
- (b) The criteria for the selection of clients and the establishment of risk status shall be defined by rule of the agency.
- (2) An advanced birth center may accept any patient who meets the criteria of subsection (1) and also may accept a patient who has:
- (a) Been screened and qualifies for trial of labor after cesarean delivery.
 - (b) A planned low-risk cesarean delivery.
 - (c) An anticipated vaginal delivery of a fetus with a

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gestational age of 37 through 41 weeks.

- $\underline{(3)}$ (a) A patient may not be accepted for care until the patient has signed a client informed-consent form.
- (b) The agency shall develop a client informed-consent form to be used by the center to inform the client of the benefits and risks related to childbirth outside a hospital.
- Section 9. Section 383.3105, Florida Statutes, is amended to read:
 - 383.3105 Patients consenting to adoptions; protocols.-
- (1) Each licensed birth center and advanced birth center facility shall adopt a protocol that at a minimum provides for birth center and advanced birth center facility staff to be knowledgeable of the waiting periods, revocation and the contents of the consent to adoption as contained in s. 63.082(4), and describes the supportive and unbiased manner in which facility staff will interact with birth parents and prospective adoptive parents regarding the adoption, in particular during the waiting period required in s. 63.082(4)(b) before consenting to an adoption.
- (2) The protocol shall be in writing and be provided upon request to any birth parent or prospective adoptive parent of a child born in the <u>birth center and advanced birth center</u> facility.
- Section 10. Section 383.311, Florida Statutes, is amended to read:

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383.311	Education	and o	rientation	for	birth	center	and
advanced birt	h center o	clients	and their	fami	ilies	_	

- (1) The clients and their families shall be fully informed of the policies and procedures of the birth center <u>or advanced</u> <u>birth center</u>, including, but not limited to, policies and procedures on:
 - (a) The selection of clients.

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- 258 (b) The expectation of self-help and family/client relationships.
 - (c) The qualifications of the clinical staff.
 - (d) The transfer to secondary or tertiary care.
- (e) The philosophy of childbirth care and the scope of services.
 - (f) The customary length of stay after delivery.
 - (2) The clients shall be prepared for childbirth and childbearing by education in:
 - (a) The course of pregnancy and normal changes occurring during pregnancy.
 - (b) The need for prenatal care.
 - (c) Nutrition, including encouragement of breastfeeding.
 - (d) The effects of smoking and substance abuse.
 - (e) Labor and delivery.
- 273 (f) The care of the newborn to include safe sleep
 274 practices and the possible causes of Sudden Unexpected Infant
 275 Death.

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

383.312 Prenatal care of birth center <u>and advanced birth</u> center clients.—

- (1) A birth center and an advanced birth center shall ensure that their 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 each client and shall be available during labor and delivery.

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

- 383.313 <u>Birth center</u> performance of laboratory and surgical services; use of anesthetic and chemical agents.—
- (1) LABORATORY SERVICES.—A birth center may collect specimens for those tests that are requested under protocol. A birth center may perform simple laboratory tests, as defined by rule of the agency, and is exempt from the requirements of chapter 483, provided no more than five physicians are employed by the birth center and testing is conducted exclusively in connection with the diagnosis and treatment of clients of the 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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include operative obstetrics or caesarean sections.

- (3) ADMINISTRATION OF ANALGESIA AND ANESTHESIA.—General and conduction anesthesia may not be administered at a birth center. Systemic analgesia may be administered, and local anesthesia for pudendal block and episiotomy repair may be performed if procedures are outlined by the clinical staff and performed by personnel with statutory authority to do so.
- (4) INTRAPARTAL USE OF CHEMICAL AGENTS.—Labor may not be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor unless prescribed by personnel with statutory authority to do so and unless in connection with and prior to emergency transport.

Section 13. Section 383.3131, Florida Statutes, is created to read:

- 383.3131 Advanced birth center performance of laboratory and surgical services; use of anesthetic and chemical agents.—
- (1) LABORATORY SERVICES.—A laboratory located in an advanced birth center is subject to the requirements of chapter 483.
- (2) SURGICAL SERVICES.—Surgical procedures shall be limited to uncomplicated cesarean deliveries, surgical management of immediate complications, and procedures normally performed during uncomplicated childbirths, such as episiotomies and repairs of vaginal lacerations. Postpartum sterilization may be performed on a patient who has given birth in the advanced

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birth center with the consent of the patient. A newborn infant may be circumcised before discharge with the consent of the parent.

to read:

- (3) ADMINISTRATION OF ANESTHESIA.—General, conduction, and local anesthesia may be administered at an advanced birth center if such services are provided in accordance with established protocol required by state law. All general anesthesia shall be administered by an anesthesiologist or a certified registered nurse anesthetist. When general anesthesia is administered, a physician or a certified registered nurse anesthetist shall be present in the advanced birthing center during the anesthesia and postanesthesia recovery period until the patient is fully alert. When anesthesia services are performed by a certified registered nurse anesthetist, a board-certified anesthesiologist shall be on call and available at all times.
- (4) INTRAPARTAL USE OF CHEMICAL AGENTS.—Labor may be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor at an advanced birth center if prescribed by personnel with statutory authority to do so.

 Labor may be electively induced at 39 weeks' gestation or later for a patient with a documented Bishop score of 8 or greater.

 Section 14. Section 383.315, Florida Statutes, is amended

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

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

- (2) Consultation may be provided onsite or by telephone, as required by clinical and geographic conditions.
- (3) An advanced birth center shall either employ or maintain an agreement with an obstetric provider with privileges to perform and who is available to attend all cesarean deliveries.

Section 15. Section 383.316, Florida Statutes, is amended to read:

383.316 Transfer and transport of clients to hospitals.-

- (1) If unforeseen complications arise during labor, delivery, or postpartum the client shall be transferred to a hospital.
- (2) Each licensed birth center or advanced birth center facility shall make arrangements with a local ambulance service licensed under chapter 401 for the transport of emergency patients to a hospital. Such arrangements shall be documented in the policy and procedures center's manual of the facility if the birth center or advanced birth center does not own or operate a licensed ambulance. The policy and procedures manual shall also contain specific protocols for the transfer of any patient to a

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376 licensed hospital.

- (3) A licensed <u>birth center or advanced birth center</u>

 facility shall identify neonatal-specific transportation services, including ground and air ambulances; list their particular qualifications; and have the telephone numbers for access to these services clearly listed and immediately available.
- (4) The birth center or advanced birth center shall assess and document Annual assessments of the transportation services and transfer protocols annually shall be made and documented.

Section 16. Section 383.318, Florida Statutes, is amended to read:

- 383.318 Postpartum care for birth center <u>and advanced</u> birth center clients and infants.—
- (1) A mother and her infant shall be dismissed from <u>a</u> the birth center within 24 hours after the birth of the infant, except in unusual circumstances as defined by rule of the agency. If a mother or <u>an</u> infant is retained at the birth center for more than 24 hours after the birth, a report shall be filed with the agency within 48 hours of the birth describing the circumstances and the reasons for the decision.
- (2) (a) A mother and her infant shall be discharged from an advanced birth center within 48 hours after the birth of the infant for a vaginal delivery and within 72 hours when delivery is by cesarean section, except in unusual circumstances defined

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401	by rule of the agency.						
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) (3) 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 birth center and advanced birth center 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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CODING: Words stricken are deletions; words underlined are additions.

requirements of part II of chapter 408, the agency shall coordinate all periodic inspections for licensure made by the agency to ensure that the cost to the <u>birth center and advanced birth center</u> facility of such inspections and the disruption of services by such inspections is minimized.

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Section 18. Section 383.327, Florida Statutes, is amended to read:

383.327 Birth and death records; reports.—<u>Each licensed</u> birth center and advanced birth center shall:

- (1) <u>File</u> a completed certificate of birth shall be filed with the local registrar within 5 days of each birth in accordance with chapter 382.
- (2) <u>Immediately report</u> each maternal death, newborn death, and stillbirth shall be reported immediately to the medical examiner.
- (3) The licensee shall Comply with all requirements of this chapter and rules promulgated hereunder.
- (4) Annually submit a report shall be submitted annually to the agency. The contents of the report shall be prescribed by rule of the agency.
- Section 19. Section 383.33, Florida Statutes, is amended to read:
- 383.33 Administrative penalties; moratorium on admissions.—
 - (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 \$500 per violation per day for the violation of any provision of ss. 383.30-383.335, part II of chapter 408, or applicable rules.

- (2) In determining the amount of the fine to be levied for a violation, as provided in this section, the following factors shall be considered:
- (a) The severity of the violation, including the probability that death or serious harm to the health or safety of any person will result or has resulted; the severity of the actual or potential harm; and the extent to which the provisions of ss. 383.30-383.335, part II of chapter 408, or applicable rules were violated.
- (b) Actions taken by the licensee to correct the violations or to remedy complaints.
 - (c) Any previous violations by the licensee.
- (3) In accordance with part II of chapter 408, the agency may impose an immediate moratorium on elective admissions to any licensed birth center or advanced birth center facility, building or portion thereof, or service when the agency determines that any condition in the center facility presents a threat to the public health or safety.
- Section 20. Section 383.332, Florida Statutes, is amended to read:
- 383.332 Establishing, managing, or operating a birth center or an advanced birth center without a license; penalty.—

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Any person who establishes, conducts, manages, or operates any birth center or advanced birth center 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.

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

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

- (11)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, 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.
- 2. The term "institutional pharmacy" includes every location in a hospital, clinic, advanced birth center, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.
- 3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification

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

- 4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.
- 5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).
- (b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner

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527	pharmacy	service	es.				

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- Section 22. Paragraph (c) of subsection (2) of section 465.019, Florida Statutes, is amended to read:
 - 465.019 Institutional pharmacies; permits.-
- (2) The following classes of institutional pharmacies are established:
- (c) "Modified Class II institutional pharmacies" are those institutional pharmacies in short-term, primary care treatment centers, including advanced birth centers, that meet all the requirements for a Class II permit, except space and equipment requirements.
- Section 23. This act shall take effect July 1, 2018.

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