

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2019

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HOUSE BILL 575  
PROPOSED COMMITTEE SUBSTITUTE H575-PCS40434-SHF-9

Short Title: Establish Birth Center Licensure Act.

(Public)

Sponsors:

Referred to:

April 4, 2019

1 A BILL TO BE ENTITLED  
2 AN ACT ESTABLISHING A LICENSURE PROCESS AND ANNUAL LICENSE FEES FOR  
3 BIRTH CENTERS.

4 The General Assembly of North Carolina enacts:

5 **SECTION 1.(a)** Article 6 of Chapter 131E of the General Statutes is amended by  
6 adding a new Part to read:

7 "Part 4A. Birth Center Licensure Act.

8 **"§ 131E-153. Title; purpose.**

9 (a) This Part shall be known as the "Birth Center Licensure Act."

10 (b) The purpose of this Part is to establish licensing requirements for birth centers that  
11 promote public health, safety, and welfare and to provide for the development, establishment,  
12 and enforcement of basic standards for the care and treatment of mothers and infants in birth  
13 centers.

14 **"§ 131E-153.1. Definitions.**

15 As used in this Part, unless otherwise specified, the following terms have the following  
16 meanings:

17 (1) Birth center. – A facility licensed for the primary purpose of performing  
18 normal, uncomplicated deliveries that is not a hospital or ambulatory surgical  
19 facility, and where births are planned to occur away from the mother's usual  
20 residence following a low-risk pregnancy.

21 (2) Commission. – The North Carolina Birth Center Commission established  
22 under G.S. 131E-153.7.

23 (3) Low-risk pregnancy. – A normal, uncomplicated prenatal course as  
24 determined by documentation of adequate prenatal care and the anticipation  
25 of a normal, uncomplicated labor and birth, as defined by reasonable and  
26 generally accepted criteria adopted by professional groups for maternal, fetal,  
27 and neonatal health care, and generally accepted by the health care providers  
28 to whom they apply.

29 **"§ 131E-153.2. Licensure requirement.**

30 (a) No person shall establish or operate a birth center in this State without obtaining a  
31 license from the Department under this Part.

32 (b) The Department shall provide applications for birth center licensure. Each application  
33 filed with the Department shall contain all of the following information:

34 (1) The name of the applicant.

35 (2) The site and location of the birth center.



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1           (3)    Documentation that the birth center meets the licensure standards adopted by  
2           the Commission pursuant to G.S. 131E-153.8.

3           (4)    Any other information the Department deems necessary.

4       (c)    Upon receipt of an application for a birth center license, the Department shall issue a  
5 license upon the recommendation of the Commission if the Department finds that the applicant  
6 is in compliance with the provisions of this Part and any rules adopted by the Commission under  
7 this Part. The license is valid for a period of one year from the date of issuance and must designate  
8 the number and types of beds and the number of rooms on the licensed premises. The Department  
9 shall charge the applicant a nonrefundable annual license fee in the amount of one hundred  
10 dollars (\$100.00). This fee shall be credited to the Department as a departmental receipt and  
11 applied to offset costs for licensing and inspecting birth centers.

12       (d)    The Department shall renew each license in accordance with rules adopted by the  
13 Commission under G.S. 131E-153.8.

14       (e)    The Department shall issue a birth center license only for the premises and persons  
15 named in the license. A birth center license is not transferable or assignable except with the  
16 written approval of the Department.

17       (f)    The operator shall post the license on the licensed premises in an area accessible to  
18 the public.

19 **"§ 131E-153.3. Adverse action on a license.**

20       (a)    The Department may deny, suspend, or revoke a license in any case when it finds a  
21 substantial failure to comply with the provisions of this Part or any rule adopted under this Part.

22       (b)    The Secretary may suspend the admission of any new patients to a birth center, or  
23 suspend the services of a birth center licensed under this Part, if the conditions of the birth center  
24 constitute a substantial failure to comply with the provisions of this Part or any rule adopted  
25 under this Part and are dangerous to the health or safety of the patients. In determining whether  
26 to suspend admissions or services under this subsection, the Secretary shall consider the  
27 following factors:

28           (1)    The nature and severity of the conditions.

29           (2)    The degree of impact of the conditions on the health and safety of its patients.

30           (3)    The nature and severity of the proposed suspension.

31           (4)    The impact that the proposed suspension would have on the functionality of  
32 the birth center and the availability of services necessary to the community or  
33 to current patients of the birth center.

34           (5)    Whether all other reasonable means for correcting the problem have been  
35 exhausted and no less restrictive alternative to suspension of admissions or  
36 services exists.

37       (c)    A birth center may contest any adverse action on its license under this section in  
38 accordance with Chapter 150B of the General Statutes.

39 **"§ 131E-153.4. Limitations of services.**

40       (a)    A birth center licensed under this Part shall not assert, represent, offer, provide, or  
41 imply that the center is rendering or may render care or services other than the services it is  
42 permitted to render within the scope of the license issued.

43       (b)    The following limitations apply to the services performed at a licensed birth center:

44           (1)    Surgical procedures are limited to those normally accomplished during an  
45 uncomplicated birth, such as episiotomy and repair, as determined by the  
46 Commission.

47           (2)    No abortions may be performed.

48           (3)    No general or conduction anesthesia may be performed.

49           (4)    No vaginal birth after cesarean (VBAC) or trial of labor after cesarean  
50 (TOLAC) may be performed.

51 **"§ 131E-153.5. Review of birth center fee schedule.**

1 Every three years, the Department shall review and, as necessary, revise the Freestanding  
2 Birth Center Fee Schedule to ensure that (i) the fees are sufficient to cover the costs of providing  
3 intrapartum, birth, postpartum, and initial newborn care and (ii) the cost for any State-mandated  
4 newborn screening is reimbursed at no less than the cost of the screening.

5 **"§ 131E-153.6. Inspections.**

6 (a) The Department shall make, or cause to be made, inspections of birth centers as it  
7 deems necessary to investigate unexpected occurrences involving death or serious physical injury  
8 and reportable adverse outcomes identified in the rules adopted by the Commission under  
9 G.S. 131E-153.8. Any birth center licensed under this Part shall, at all times, be subject to  
10 inspections by the Department according to the rules of the Commission.

11 (b) Authorized representatives of the Department shall have, at all times, the right of  
12 proper entry upon any and all parts of the premises of any place in which entry is necessary to  
13 carry out the provisions of this Part or the rules adopted by the Commission, and it shall be  
14 unlawful for any person to resist a proper entry by such authorized representative upon any  
15 premises other than a private dwelling. However, no representative shall, by this entry onto the  
16 premises, endanger the health or well-being of any patient being treated in the birth center.

17 (c) To enable the Department to determine compliance with this Part and with the rules  
18 adopted by the Commission under this Part, and to investigate complaints made against a birth  
19 center licensed under this Part, the Department has the authority to investigate birth centers in  
20 the same manner as it investigates hospitals under G.S. 131E-80(d).

21 (d) Information received by the Commission and the Department through filed reports,  
22 license applications, or inspections that are required or authorized by the provisions of this Part  
23 may be disclosed publicly except where this disclosure would violate applicable laws concerning  
24 patient records and patient confidentiality. However, no such public disclosure shall identify the  
25 patient involved without permission of the patient or court order.

26 **"§ 131E-153.7. North Carolina Birth Center Commission; composition; powers and duties.**

27 (a) There is created the North Carolina Birth Center Commission of the Department of  
28 Health and Human Services. The Commission has the power and duty to do the following:

29 (1) Adopt rules establishing standards for the licensure, operation, and regulation  
30 of birth centers within the State in a manner consistent with the provisions and  
31 purposes of this Part.

32 (2) Review and make recommendations to the Department about whether to  
33 approve or disapprove birth center license applications.

34 (b) The Commission shall consist of seven members appointed as follows:

35 (1) The North Carolina Obstetrical and Gynecological Society shall elect six  
36 members who are licensed physicians providing obstetric care with a  
37 minimum of two years' experience working with birth centers.

38 a. The North Carolina Obstetrical and Gynecological Society shall send  
39 the names of four of the elected members to the Governor who shall  
40 appoint two members to the Commission.

41 b. The North Carolina Obstetrical and Gynecological Society shall send  
42 the names of two members to the Speaker of the House of  
43 Representatives who shall appoint one member to the Commission.

44 (2) The North Carolina Affiliate of the American College of Nurse-Midwives  
45 shall elect six members who are certified midwives providing obstetric care  
46 with a minimum of two years' experience working with birth centers.

47 a. The North Carolina Affiliate of the American College of  
48 Nurse-Midwives shall send the names of four of the elected members  
49 to the Governor who shall appoint two members to the Commission.

50 b. The North Carolina Affiliate of the American College of  
51 Nurse-Midwives shall send the names of two members to the President

1 Pro Tempore of the Senate who shall appoint one member to the  
2 Commission.

- 3 (3) The Governor shall appoint one public member. The public member shall not  
4 be eligible for appointment under subdivisions (1) and (2) of this subsection,  
5 but shall have professional experience and familiarity with the administrative  
6 aspects of obstetrical care practices or facilities, including, but not limited to,  
7 birth centers.

8 Any appointment to fill a vacancy on the Commission created by the resignation, dismissal,  
9 death, or disability of a member shall be for the balance of the unexpired term.

10 (c) Members appointed pursuant to subsection (b) of this section shall serve for a term of  
11 four years and no member shall serve more than two consecutive terms.

12 (d) The Governor may remove any member of the Commission from office for  
13 misfeasance, malfeasance, or nonfeasance in accordance with the provisions of G.S. 143B-13 of  
14 the Executive Organization Act of 1973.

15 (e) Vacancies on the Commission among the membership nominated by the North  
16 Carolina Obstetrical and Gynecological Society or the North Carolina Affiliate of the American  
17 College of Nurse-Midwives shall be filled by the executive committee or other authorized agent  
18 of said organization until the next meeting of the organization, at which time the organization  
19 shall nominate a member to fill the vacancy for the unexpired term.

20 (f) The members of the Commission shall receive per diem and necessary travel and  
21 subsistence expenses in accordance with the provisions of G.S. 138-5.

22 (g) A majority of the Commission shall constitute a quorum for the transaction of  
23 business.

24 (h) All clerical and other services required by the Commission shall be supplied by the  
25 Secretary of Health and Human Services.

26 **§ 131E-153.8. Rules.**

27 (a) The North Carolina Birth Center Commission shall adopt rules establishing the  
28 following requirements for all birth centers seeking a license to operate in the State:

- 29 (1) Accreditation. – A requirement that the birth center obtain and maintain  
30 accreditation with the Commission for the Accreditation of Birth Centers  
31 (CABC) and provide the following related information to the Department:

- 32 a. All documentation required for accreditation by the CABC shall be  
33 submitted as part of a licensure application.  
34 b. Copies of interim status reports provided to the CABC shall be  
35 submitted within 15 days after the reports are provided to the CABC.  
36 c. Copies of all reports and responses from CABC regarding  
37 reaccreditation site visits shall be submitted within 15 days after  
38 receipt.  
39 d. Information about root cause analysis, remedial action, or training  
40 associated with unexpected occurrences involving death or serious  
41 physical injury and reportable adverse outcomes shall be submitted  
42 within 15 days after completion of the analysis, remedial action, or  
43 training.  
44 e. A notification of loss of CABC accreditation shall be immediately  
45 reported to the Department.

- 46 (2) Risk status. – A requirement that the birth center establish procedures  
47 specifying the criteria by which each pregnant person's risk status will be  
48 evaluated at admission and during labor, pursuant to CABC standards.

- 49 (3) Second trimester ultrasound. – A requirement that the birth center recommend  
50 an ultrasound during the second trimester of pregnancy, ideally when the  
51 pregnant person is between 18 and 22 weeks pregnant, consistent with

1 recommendations of the American College of Obstetricians and  
2 Gynecologists concerning ultrasound in pregnancy. If a pregnant person  
3 declines this screening test, the birth center shall document the informed  
4 refusal in the medical record.

5 (4) Targeted ultrasound. – A requirement that the birth center conduct a targeted  
6 ultrasound for further evaluation of maternal-fetal health consistent with those  
7 indications included in the recommendations of the American College of  
8 Obstetricians and Gynecologists concerning ultrasound practice in pregnancy.  
9 If a pregnant person receiving care at a licensed birth center and intending to  
10 give birth out-of-hospital declines a targeted ultrasound for maternal or fetal  
11 indications, the birth center shall deem the pregnant person ineligible for  
12 intrapartum care at the birth center, inform the patient of this determination in  
13 writing, and refer the person for a hospital birth.

14 (5) Transfer of patients to higher levels of care. – A requirement that the birth  
15 center develop and submit as part of the licensure application process a plan  
16 for complying with the standards of the Commission for Accreditation of Birth  
17 Centers with respect to transfer of care procedures.

18 (6) Sentinel events and adverse outcomes. – Each licensed birth center shall report  
19 unexpected occurrences involving death or serious physical injury and any  
20 other adverse outcomes identified by the Commission, to the CABG and the  
21 Department within a timeframe established by the Commission. For each  
22 occurrence, the birth center shall conduct root cause analysis, remedial action,  
23 training, or a combination of these, to address these occurrences as per CABG  
24 guidelines. The Department shall investigate all unexpected occurrences  
25 involving death or serious physical injury and all reportable adverse outcomes  
26 identified by the Commission in the rules.

27 (7) Reporting requirements. – A requirement and standards for licensed birth  
28 centers to regularly report outcome and other data that the Commission shall  
29 analyze and distribute on a regular basis.

30 (b) The Department shall enforce this Part and any rules adopted by the Commission  
31 under this Part.

32 **"§ 131E-153.9. Confidential Information.**

33 The Commission, its members, and staff, may release confidential or nonpublic information  
34 to any health care licensure board in this State, or another state, or authorized North Carolina  
35 Department of Health and Human Services personnel with enforcement or investigative  
36 responsibilities concerning issuance, denial, annulment, suspension, or revocation of a license,  
37 or the voluntary surrender of a license by a licensee of the Commission, including the reasons  
38 for the action, or an investigative report made by the Commission. The Commission shall notify  
39 the licensee within 60 days after the information is transmitted. A summary of the information  
40 that is being transmitted shall be furnished to the licensee. If the licensee requests in writing  
41 within 30 days after being notified that the information has been transmitted, the licensee shall  
42 be furnished a copy of all information so transmitted. The notice or copies of the information  
43 shall not be provided if the information relates to an ongoing criminal investigation by any law  
44 enforcement agency or authorized Department of Health and Human Services personnel with  
45 enforcement or investigative responsibilities."

46 **SECTION 1.(b)** By October 1, 2019, the Department of Health and Human Services  
47 shall review and, as necessary, revise its current Freestanding Birth Center Fee Schedule to  
48 ensure that (i) the fees are sufficient to cover the costs of providing intrapartum, birth,  
49 postpartum, and initial newborn care and (ii) the cost for any State-mandated newborn screening  
50 is reimbursed at no less than the cost of the screening.

1           **SECTION 1.(c)** The initial appointments under G.S. 131E-153.7(b) shall be made  
2 not later than 60 days after the effective date of this act. In order to provide for staggering of  
3 terms under G.S. 131E-153.7(b), the initial term of office for each member appointed under  
4 G.S. 131E-153.7(b)(1)a. and (b)(2)b. shall be two years. The initial term of office for each  
5 member appointed under G.S. 131E-153.7(b)(1)b. and (b)(2)a. shall be three years, and the initial  
6 term for the member appointed under G.S. 131E-153.7(b)(3) shall be one year. Subsequent  
7 appointments shall be for the full four-year term in accordance with G.S. 131E-153.7(c). The  
8 partial term to provide for the initial staggering of terms shall not count as full terms for purposes  
9 of the limitation in G.S. 131E-153.7(c).

10           **SECTION 2.** This act becomes effective July 1, 2019, and applies to licenses granted  
11 one year after the rules promulgated by the Commission are adopted. The Codifier of Rules shall  
12 notify the Revisor of Statutes of the effective date of rules adopted as required by this act.