

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2019

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HOUSE BILL 575*
Committee Substitute Favorable 4/30/19
Committee Substitute #2 Favorable 6/26/19

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-153.5. Review of birth center fee schedule.

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

34 "§ 131E-153.6. Inspections.



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

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

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

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

21 **"§ 131E-153.7. North Carolina Birth Center Commission; composition; powers and duties.**

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

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

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

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

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

33 a. The North Carolina Obstetrical and Gynecological Society shall send
34 the names of four of the elected members to the Governor who shall
35 appoint two members to the Commission.

36 b. The North Carolina Obstetrical and Gynecological Society shall send
37 the names of two members to the Speaker of the House of
38 Representatives and one member shall be appointed by the General
39 Assembly upon the recommendation of the Speaker of the House of
40 Representatives, as provided in G.S. 120-121.

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

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

47 b. The North Carolina Affiliate of the American College of
48 Nurse-Midwives shall send the names of two members to the President
49 Pro Tempore of the Senate and one member shall be appointed by the
50 General Assembly upon the recommendation of the President Pro
51 Tempore of the Senate, as provided in G.S. 120-121.

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

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

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

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

13 (e) A vacancy on the Commission created by death, resignation, or otherwise, shall be
14 filled in the same manner as the original appointment, except that all unexpired terms of
15 Commission members appointed by the General Assembly shall be filled in accordance with
16 G.S. 120-122. Appointees to fill vacancies shall serve the remainder of the unexpired term and
17 until their successors are appointed and qualified.

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

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

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

24 **"§ 131E-153.8. Rules.**

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

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

30 a. All documentation required for accreditation by the CABC shall be
31 submitted as part of a licensure application.

32 b. Copies of interim status reports provided to the CABC shall be
33 submitted within 15 days after the reports are provided to the CABC.

34 c. Copies of all reports and responses from CABC regarding
35 reaccreditation site visits shall be submitted within 15 days after
36 receipt.

37 d. Information about root cause analysis, remedial action, or training
38 associated with unexpected occurrences involving death or serious
39 physical injury and reportable adverse outcomes shall be submitted
40 within 15 days after completion of the analysis, remedial action, or
41 training.

42 e. A notification of loss of CABC accreditation shall be immediately
43 reported to the Department.

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

47 (3) Second trimester ultrasound. – A requirement that the birth center recommend
48 an ultrasound during the second trimester of pregnancy, ideally when the
49 pregnant person is between 18 and 22 weeks pregnant, consistent with
50 recommendations of the American College of Obstetricians and
51 Gynecologists concerning ultrasound in pregnancy. If a pregnant person

1 declines this screening test, the birth center shall document the informed
2 refusal in the medical record.

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

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

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

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

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

30 **"§ 131E-153.9. Confidential information.**

31 The Commission, its members, and staff, may release confidential or nonpublic information
32 to any health care licensure board in this State, or another state, or authorized North Carolina
33 Department of Health and Human Services personnel with enforcement or investigative
34 responsibilities concerning issuance, denial, annulment, suspension, or revocation of a license,
35 or the voluntary surrender of a license by a licensee of the Commission, including the reasons
36 for the action, or an investigative report made by the Commission."

37 **SECTION 1.(b)** Article 6 of Chapter 131E, Part 4A of the General Statutes is
38 amended by adding new sections to read:

39 **"§ 131E-153.2. Licensure requirement.**

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

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

44 (1) The name of the applicant.

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

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

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

49 (c) Upon receipt of an application for a birth center license, the Department shall issue a
50 license upon the recommendation of the Commission if the Department finds that the applicant
51 is in compliance with the provisions of this Part and any rules adopted by the Commission under

1 this Part. The license is valid for a period of one year from the date of issuance and must designate
2 the number and types of beds and the number of rooms on the licensed premises. The Department
3 shall charge the applicant a nonrefundable annual license fee in the amount of four hundred
4 dollars (\$400.00) plus a nonrefundable annual per-birthing room fee of seventeen dollars and
5 fifty cents (\$17.50). This fee shall be credited to the Department as a departmental receipt and
6 applied to offset costs for licensing and inspecting birth centers.

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

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

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

14 (g) Notwithstanding subsection (a) of this section, birth centers that are operating in this
15 State on the date this act becomes effective and that are accredited by the Commission for the
16 Accreditation of Birth Centers (CABC) and that remain continually accredited, shall be allowed
17 to continue operations as the Commission is constituted and promulgates permanent rules. Within
18 90 days of the effective date of the Commission's permanent rules regarding licensure
19 applications, such unlicensed birth centers operating in this State shall submit a completed
20 licensure application, together with the requisite fee, to the Division of Health Service
21 Regulation. The application and fee shall be received or postmarked no later than 90 days after
22 the rules promulgated by the Commission are adopted.

23 **"§ 131E-153.3. Adverse action on a license.**

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

26 (b) The Secretary or a designee may suspend the admission of any new patients to a birth
27 center if the conditions of the birth center are detrimental to the health or safety of any patient.
28 This suspension shall remain in effect until the Secretary, or the Secretary's designee, is satisfied
29 that conditions or circumstances merit the removal of the suspension. The authority under this
30 subsection is in addition to the authority to suspend or revoke the license of a birth center.

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

33 **"§ 131E-153.4. Limitations of services.**

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

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

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

41 (2) No abortions may be performed.

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

43 (4) No vaginal birth after cesarean (VBAC) or trial of labor after cesarean
44 (TOLAC) may be performed."

45 **SECTION 1.(c)** Article 6 of Chapter 131E, Part 4A of the General Statutes is
46 amended by adding a new section to read:

47 **"§ 131E-153.10. Penalties.**

48 A person who owns, in whole or in part, or operates a birth center without a license is guilty
49 of a Class 3 misdemeanor and upon conviction is subject only to a fine of not more than fifty
50 dollars (\$50.00) for the first offense and not more than five hundred dollars (\$500.00) for each

1 subsequent offense. Each day of continuing violation after conviction is considered a separate
2 offense."

3 **SECTION 1.(d)** By October 1, 2019, the Department of Health and Human Services
4 shall review and, as necessary, revise its current Freestanding Birth Center Fee Schedule to
5 ensure that (i) the fees are sufficient to cover the costs of providing intrapartum, birth,
6 postpartum, and initial newborn care and (ii) the cost for any State-mandated newborn screening
7 is reimbursed at no less than the cost of the screening. The Department shall also develop a birth
8 center licensure application containing the elements outlined in G.S. 131E-153.2(b) and shall
9 make it available upon adoption of the rules by the North Carolina Birth Center Commission.

10 **SECTION 1.(e)** The initial appointments to the North Carolina Birth Center
11 Commission under G.S. 131E-153.7(b) shall be made not later than 60 days after the effective
12 date of this act. In order to provide for staggering of terms under G.S. 131E-153.7(b), the initial
13 term of office for each member appointed under G.S. 131E-153.7(b)(1)a. and (b)(2)b. shall be
14 two years. The initial term of office for each member appointed under G.S. 131E-153.7(b)(1)b.
15 and (b)(2)a. shall be three years, and the initial term for the member appointed under
16 G.S. 131E-153.7(b)(3) shall be one year. Subsequent appointments shall be for the full four-year
17 term in accordance with G.S. 131E-153.7(c). The partial terms to provide for the initial
18 staggering of terms shall not count as full terms for purposes of the limitation in
19 G.S. 131E-153.7(c).

20 **SECTION 2.** The criminal offense in G.S. 131E-153.6(b), as enacted by Section 1(a)
21 of this act, becomes effective December 1, 2019, and applies to offenses committed on or after
22 that date. Section 1(b) of this act becomes effective one year after the rules promulgated by the
23 North Carolina Birth Center Commission are adopted and applies to licenses granted on or after
24 that date. Section 1(c) of this act becomes effective one year after the rules promulgated by the
25 North Carolina Birth Center Commission are adopted and applies to criminal offenses committed
26 on or after that date. The Codifier of Rules shall notify the Revisor of Statutes of the effective
27 date of rules adopted as required by this act. Except as otherwise provided, this act is effective
28 when it becomes law.