

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2021

H.B. 39
Feb 1, 2021
HOUSE PRINCIPAL CLERK

H

D

HOUSE BILL DRH30030-MGf-50

Short Title: Establish Birth Center Licensure Act.

(Public)

Sponsors: Representative White.

Referred to:

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.**

35 (a) The Department shall make, or cause to be made, inspections of birth centers as it
36 deems necessary to investigate unexpected occurrences involving death or serious physical injury



1 and reportable adverse outcomes identified in the rules adopted by the Commission under
2 G.S. 131E-153.8. Any birth center licensed under this Part shall, at all times, be subject to
3 inspections by the Department according to the rules of the Commission.

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

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

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

19 **"§ 131E-153.7. North Carolina Birth Center Commission; composition; powers and duties.**

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

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

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

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

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

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

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

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

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

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

50 (3) The Governor shall appoint one public member. The public member shall not
51 be eligible for appointment under subdivisions (1) and (2) of this subsection

1 but shall have professional experience and familiarity with the administrative
2 aspects of obstetrical care practices or facilities, including, but not limited to,
3 birth centers.

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

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

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

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

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

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

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

22 **"§ 131E-153.8. Rules.**

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

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

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

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

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

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

40 e. A notification of loss of CABC accreditation shall be immediately
41 reported to the Department.

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

45 (3) Second trimester ultrasound. – A requirement that the birth center recommend
46 an ultrasound during the second trimester of pregnancy, ideally when the
47 pregnant person is between 18 and 22 weeks pregnant, consistent with
48 recommendations of the American College of Obstetricians and
49 Gynecologists concerning ultrasound in pregnancy. If a pregnant person
50 declines this screening test, the birth center shall document the informed
51 refusal in the medical record.

- 1 (4) Targeted ultrasound. – A requirement that the birth center conduct a targeted
2 ultrasound for further evaluation of maternal-fetal health consistent with those
3 indications included in the recommendations of the American College of
4 Obstetricians and Gynecologists concerning ultrasound practice in pregnancy.
5 If a pregnant person receiving care at a licensed birth center and intending to
6 give birth out-of-hospital declines a targeted ultrasound for maternal or fetal
7 indications, the birth center shall deem the pregnant person ineligible for
8 intrapartum care at the birth center, inform the patient of this determination in
9 writing, and refer the person for a hospital birth.
- 10 (5) Transfer of patients to higher levels of care. – A requirement that the birth
11 center develop and submit as part of the licensure application process a plan
12 for complying with the standards of the Commission for Accreditation of Birth
13 Centers with respect to transfer of care procedures.
- 14 (6) Sentinel events and adverse outcomes. – Each licensed birth center shall report
15 unexpected occurrences involving death or serious physical injury and any
16 other adverse outcomes identified by the Commission to the CABC and the
17 Department within a time frame established by the Commission. For each
18 occurrence, the birth center shall conduct root cause analysis, remedial action,
19 training, or a combination of these, to address these occurrences as per CABC
20 guidelines. The Department shall investigate all unexpected occurrences
21 involving death or serious physical injury and all reportable adverse outcomes
22 identified by the Commission in the rules.
- 23 (7) Reporting requirements. – A requirement and standards for licensed birth
24 centers to regularly report outcome and other data that the Commission shall
25 analyze and distribute on a regular basis.

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

28 **"§ 131E-153.9. Confidential information.**

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

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

37 **"§ 131E-153.2. Licensure requirement.**

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

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

- 42 (1) The name of the applicant.
43 (2) The site and location of the birth center.
44 (3) Documentation that the birth center meets the licensure standards adopted by
45 the Commission pursuant to G.S. 131E-153.8.
46 (4) Any other information the Department deems necessary.

47 (c) Upon receipt of an application for a birth center license, the Department shall issue a
48 license upon the recommendation of the Commission if the Department finds that the applicant
49 is in compliance with the provisions of this Part and any rules adopted by the Commission under
50 this Part. The license is valid for a period of one year from the date of issuance and must designate
51 the number and types of beds and the number of rooms on the licensed premises. The Department

1 shall charge the applicant a nonrefundable annual license fee in the amount of four hundred
2 dollars (\$400.00) plus a nonrefundable annual per-birthing room fee of seventeen dollars and
3 fifty cents (\$17.50). This fee shall be credited to the Department as a departmental receipt and
4 applied to offset costs for licensing and inspecting birth centers.

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

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

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

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

21 **"§ 131E-153.3. Adverse action on a license.**

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

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

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

31 **"§ 131E-153.4. Limitations of services.**

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

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

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

39 (2) No abortions may be performed.

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

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

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

45 **"§ 131E-153.10. Penalties.**

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

1 **SECTION 1.(d)** By October 1, 2021, the Department of Health and Human Services
2 shall review and, as necessary, revise its current Freestanding Birth Center Fee Schedule to
3 ensure that (i) the fees are sufficient to cover the costs of providing intrapartum, birth,
4 postpartum, and initial newborn care and (ii) the cost for any State-mandated newborn screening
5 is reimbursed at no less than the cost of the screening. The Department shall also develop a birth
6 center licensure application containing the elements outlined in G.S. 131E-153.2(b) and shall
7 make it available upon adoption of the rules by the North Carolina Birth Center Commission.

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

18 **SECTION 2.** The criminal offense in G.S. 131E-153.6(b), as enacted by Section 1(a)
19 of this act, becomes effective December 1, 2021, and applies to offenses committed on or after
20 that date. Section 1(b) of this act becomes effective one year after the rules promulgated by the
21 North Carolina Birth Center Commission are adopted and applies to licenses granted on or after
22 that date. Section 1(c) of this act becomes effective one year after the rules promulgated by the
23 North Carolina Birth Center Commission are adopted and applies to criminal offenses committed
24 on or after that date. The Codifier of Rules shall notify the Revisor of Statutes of the effective
25 date of rules adopted as required by this act. Except as otherwise provided, this act is effective
26 when it becomes law.