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SENATE BILL DRS55067-MGF-4D*

Short Title: Establish Birth Center Licensure Act. (Public)

Sponsors: Senators Hise, Krawiec, and Woodard (Primary Sponsors).

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, and where births are
19 planned to occur away from the mother's usual residence following a low-risk
20 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.



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 three
36 members who are licensed physicians providing obstetric care with a
37 minimum of two years' experience working with birth centers.

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

41 (3) The Governor shall appoint one public member.

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

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

47 (d) Vacancies on the Commission among the membership nominated by the North
48 Carolina Obstetrical and Gynecological Society or the North Carolina Affiliate of the American
49 College of Nurse-Midwives shall be filled by the Executive Committee or other authorized agent
50 of said organization until the next meeting of the organization, at which time the organization
51 shall nominate a member to fill the vacancy for the unexpired term.

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

3 (f) A majority of the Commission shall constitute a quorum for the transaction of
4 business.

5 (g) All clerical and other services required by the Commission shall be supplied by the
6 Secretary of Health and Human Services.

7 **"§ 131E-153.8. Rules.**

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

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

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

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

17 c. Copies of all reports and responses from CABC regarding
18 reaccreditation site visits shall be submitted within 15 days after
19 receipt.

20 d. Information about root cause analysis, remedial action, or training
21 associated with unexpected occurrences involving death or serious
22 physical injury and reportable adverse outcomes shall be submitted
23 within 15 days after completion of the analysis, remedial action, or
24 training.

25 e. A notification of loss of CABC accreditation shall be immediately
26 reported to the Department.

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

30 (3) Second trimester ultrasound. – A requirement that the birth center recommend
31 an ultrasound during the second trimester of pregnancy, ideally when the
32 pregnant person is between 18 and 22 weeks pregnant, consistent with
33 recommendations of the American College of Obstetricians and
34 Gynecologists concerning ultrasound in pregnancy. If a pregnant person
35 declines this screening test, the birth center shall document the informed
36 refusal in the medical record.

37 (4) Targeted ultrasound. – A requirement that the birth center conduct a targeted
38 ultrasound for further evaluation of maternal-fetal health consistent with those
39 indications included in the recommendations of the American College of
40 Obstetricians and Gynecologists concerning ultrasound practice in pregnancy.
41 If a pregnant person receiving care at a licensed birth center and intending to
42 give birth out of hospital declines a targeted ultrasound for maternal or fetal
43 indications, the birth center shall deem the pregnant person ineligible for
44 intrapartum care at the birth center, inform the patient of this determination in
45 writing, and refer the person for a hospital birth.

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

50 (6) Sentinel events and adverse outcomes. – Each licensed birth center shall report
51 unexpected occurrences involving death or serious physical injury and any

1 other adverse outcomes identified by the Commission, to the CABC and the
2 Department within 15 days after the occurrence. For each occurrence, the birth
3 center shall conduct root cause analysis, remedial action, training, or a
4 combination of these, to address these occurrences as per CABC guidelines.
5 The Department shall investigate all unexpected occurrences involving death
6 or serious physical injury and all reportable adverse outcomes identified by
7 the Commission in the rules.

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

11 (b) The Department shall enforce this Part and any rules adopted by the Commission
12 under this Part."

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

18 **SECTION 2.** This act becomes effective July 1, 2019.