

Reported 3/3/87

FEB 20 1987

HOUSE FILE 328

Place On Calendar

BY COMMITTEE ON HUMAN RESOURCES

(Formerly House File 96)-

Passed House, Date 3-3-87 (p.507) Passed Senate, Date _____

Vote: Ayes 89 Nays 11 Vote: Ayes _____ Nays _____

Approved _____

A BILL FOR

1 An Act relating to the licensure and regulation of birth centers
2 and providing penalties.

3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 328

1 Section 1. NEW SECTION. 135G.1 LICENSURE AND REGULATION
2 OF BIRTH CENTERS -- LEGISLATIVE INTENT.

3 It is the intent of the general assembly to provide for the
4 protection of public health and safety in the establishment,
5 construction, maintenance, and operation of birth centers by
6 providing for licensure of birth centers and for the develop-
7 ment, establishment, and enforcement of minimum standards with
8 respect to birth centers.

9 Sec. 2. NEW SECTION. 135G.2 DEFINITIONS.

10 As used in this chapter, unless the context otherwise re-
11 quires:

12 1. "Birth center" means any facility, institution, or
13 place, which is not an ambulatory surgical center or a
14 hospital or in a hospital, in which births are planned to
15 occur away from the mother's usual residence following a
16 normal, uncomplicated, low-risk pregnancy.

17 2. "Clinical staff" means individuals employed full time
18 or part time by a birth center who are licensed or certified
19 to provide care at childbirth, which includes the clinical
20 director.

21 3. "Consultant" means a physician licensed under chapter
22 148, 150, or 150A who agrees to provide medical and
23 obstetrical advice and services to a birth center and who
24 either:

25 a. Is certified or eligible for certification by the
26 American board of obstetrics and gynecology, or

27 b. Has hospital obstetrical privileges.

28 4. "Department" means the department of inspections and
29 appeals.

30 5. "Governing body" means any individual, group, corpora-
31 tion, or institution which is responsible for the overall
32 operation and maintenance of a birth center.

33 6. "Political subdivision" means the state or any county,
34 municipality, or other entity or subdivision of government.

35 7. "Licensed birth center" means a birth center licensed

1 in accordance with section 135G.4.

2 8. "Low-risk pregnancy" means a pregnancy which is ex-
3 pected to result in an uncomplicated birth, as determined
4 through risk criteria developed by departmental rule, and
5 which is accompanied by adequate prenatal care.

6 9. "Person" means person as defined in section 4.1, sub-
7 section 13.

8 10. "Premises" means those buildings, beds, and facilities
9 located at the main address of the licensee and all other
10 buildings, beds, and facilities for the provision of maternity
11 care located in such reasonable proximity to the main address
12 of the licensee as to appear to the public to be under the
13 dominion and control of the licensee.

14 Sec. 3. NEW SECTION. 135G.3 LICENSURE REQUIREMENT FOR
15 BIRTH CENTERS.

16 1. A person or governmental unit shall not establish, con-
17 duct, or maintain a birth center in this state without first
18 obtaining a license under section 135G.4.

19 2. A person shall not use or advertise to the public, in
20 any way or by any medium whatsoever, any facility as a birth
21 center unless such facility has first secured a license under
22 section 135G.4.

23 Sec. 4. NEW SECTION. 135G.4 LICENSURE -- ISSUANCE,
24 RENEWAL, DENIAL, SUSPENSION, REVOCATION -- FEES.

25 1. a. The department shall not issue a birth center
26 license to any applicant until:

27 (1) The department has ascertained that the staff and
28 equipment of the birth center is adequate to provide the care
29 and services required of a birth center.

30 (2) The birth center has been inspected by the state fire
31 marshal or a deputy appointed by the fire marshal for that
32 purpose, who may be a member of a municipal fire department,
33 and the department has received either a certificate of
34 compliance or a provisional certificate of compliance by the
35 birth center with the fire-hazard and fire-safety rules and

1 standards of the department as promulgated by the fire
2 marshal. The state fire marshal shall adopt rules relating to
3 fire-hazard and fire safety standards pursuant to chapter 17A
4 which shall not exceed the provision of smoke alarms, fire
5 extinguishers, sprinkler systems, and fire escape routes and
6 necessary rules which parallel state or local building code
7 rules.

8 The rules and standards promulgated by the fire marshal
9 shall be substantially in keeping with the latest generally
10 recognized safety criteria for the birth centers covered, of
11 which the applicable criteria recommended and published from
12 time to time by the national fire protection association shall
13 be prima facie evidence.

14 The state fire marshal or the fire marshal's deputy may
15 issue successive provisional certificates of compliance for
16 periods of one year each to a birth center which is in
17 substantial compliance with the applicable fire-hazard and
18 fire-safety rules and standards, upon satisfactory evidence of
19 an intent, in good faith, by the owner or operator of the
20 birth center to correct the deficiencies noted upon inspection
21 within a reasonable period of time as determined by the state
22 fire marshal or the fire marshal's deputy. Renewal of a
23 provisional certificate shall be based on a showing of
24 substantial progress in eliminating deficiencies noted upon
25 the last previous inspection of the birth center without the
26 appearance of additional deficiencies other than those arising
27 from changes in the fire-hazard and fire-safety rules,
28 regulations and standards which have occurred since the last
29 previous inspection, except that substantial progress toward
30 achievement of a good-faith intent by the owner or operator to
31 replace the entire facility within a reasonable period of
32 time, as determined by the state fire marshal or the fire
33 marshal's deputy, may be accepted as a showing of substantial
34 progress in eliminating deficiencies, for the purposes of this
35 section.

1 b. A provisional license may be issued to any birth center
2 that is in substantial compliance with this chapter and with
3 the rules adopted by the department. A provisional license
4 may be granted for a period of no more than one year from the
5 effective date of rules adopted by the department, shall
6 expire automatically at the end of its term, and shall not be
7 renewed.

8 c. A license, unless sooner suspended or revoked, auto-
9 matically expires one year from its date of issuance and is
10 renewable upon application for renewal and payment of the fee
11 prescribed, provided the applicant and the birth center meet
12 the requirements established under this chapter and by rules
13 adopted by the department. A complete application for renewal
14 of a license shall be made ninety days prior to expiration of
15 the license on forms provided by the department.

16 2. An application for a license, or renewal thereof, shall
17 be made to the department upon forms provided by the
18 department and shall contain information the department may
19 require.

20 3. a. Each application for a birth center license, or re-
21 newal thereof, shall be accompanied by a license fee. Fees
22 shall be established by rule of the department. Such fees
23 shall be deposited in the general fund of the state.

24 b. The fees established shall be based on actual costs in-
25 curred by the department in the administration of its duties
26 under this chapter.

27 4. Each license is valid only for the person or govern-
28 mental unit to whom or which the license is issued and is not
29 subject to sale, assignment, or other transfer, voluntary, or
30 involuntary; and is not valid for any premises other than
31 those for which the license was originally issued.

32 5. Each license shall be posted in a conspicuous place on
33 the licensed premises.

34 6. The department may deny, suspend, or revoke a license
35 when the department finds that there has been a substantial

1 failure to comply with the requirements established under this
2 chapter or by administrative rule.

3 Sec. 5. NEW SECTION. 135G.5 ADMINISTRATION OF BIRTH
4 CENTER.

5 1. Each licensed birth center shall have a governing body
6 which is responsible for the overall operation and maintenance
7 of the birth center.

8 a. The governing body shall develop a table of
9 organization which shows the structure of the birth center and
10 identifies the governing body, the birth center director, the
11 clinical director, the clinical staff, the medical consultant,
12 and other administrative positions.

13 b. The governing body shall develop and make available to
14 staff, clinicians, consultants, and licensing authorities, a
15 manual which documents policies, procedures, and protocols,
16 including the roles and responsibilities of all personnel.

17 2. There shall be an adequate number of licensed personnel
18 as determined by departmental rule to provide clinical
19 services needed by mothers and newborns and a sufficient
20 number of qualified personnel as determined by departmental
21 rule to provide services for families and to maintain the
22 birth center.

23 3. All clinical staff members and consultants shall hold
24 current and valid licenses from this state to practice their
25 respective disciplines.

26 4. The governing body shall adopt bylaws for the birth
27 center which shall include recommendations for clinical staff
28 or consultation appointments, delineation of clinical
29 privileges, and the organization of the clinical staff.

30 Sec. 6. NEW SECTION. 135G.6 BIRTH CENTER AND EQUIPMENT -
31 -REQUIREMENTS.

32 1. A licensed birth center shall be so designed to assure
33 adequate provision for birthing rooms, bath and toilet fa-
34 cilities, storage areas for supplies and equipment, examina-
35 tion areas, and reception or family areas. Handwashing

1 facilities shall be in, or immediately adjacent to, all
2 examining areas and birthing rooms.

3 2. a. A licensed birth center shall be equipped with
4 those items needed to provide low-risk maternity care and
5 readily available equipment to initiate emergency procedures
6 in life-threatening events to mother and baby, as defined by
7 departmental rule.

8 b. Provisions shall be made, on or off the premises, for
9 laundry, sterilization of supplies and equipment, laboratory
10 examinations, and light snacks. If a food service is pro-
11 vided, special requirements shall be met as defined by de-
12 partmental rule.

13 3. a. A licensed birth center shall be maintained in a
14 safe, clean, and orderly manner.

15 b. The governing body shall ensure that there is compli-
16 ance with fire safety provisions required by the state.

17 Sec. 7. NEW SECTION. 135G.7 MINIMUM STANDARDS FOR BIRTH
18 CENTERS -- RULES AND ENFORCEMENT.

19 The department shall adopt rules pursuant to chapter 17A to
20 administer this chapter. The rules shall be subject to
21 approval by the board of health prior to adoption by the
22 department of inspections and appeals. The department shall
23 adopt and enforce rules setting minimum standards for birth
24 centers. However, the standards shall parallel and shall not
25 exceed standards adopted by the maternity center association,
26 and state and local building codes where applicable,
27 including:

28 1. Sufficient numbers and qualified types of personnel and
29 occupational disciplines are available at all times to provide
30 necessary and adequate patient care and safety.

31 2. Infection control, housekeeping, sanitary conditions,
32 disaster plan, and medical record procedures which adequately
33 protect patient care and provide safety are established and
34 implemented.

35 3. Licensed birth centers are established, organized, and

1 operated consistent with established programmatic standards in
2 accordance with the maternity center association.

3 Sec. 8. NEW SECTION. 135G.8 SELECTION OF CLIENTS -- IN-
4 FORMED CONSENT.

5 1. a. A licensed birth center may accept only those pa-
6 tients who are expected to have normal pregnancies, labors,
7 and deliveries.

8 b. The criteria for the selection of clients and the es-
9 tablishment of risk status shall be defined by departmental
10 rule, which shall reflect risk status standards adopted by the
11 maternity center association.

12 2. a. A patient may not be accepted for care until the
13 patient has signed a client informed-consent form.

14 b. The department shall develop a client informed-consent
15 form to be used by the center to inform the client of the
16 benefits and risk related to childbirth outside a hospital.

17 Sec. 9. NEW SECTION. 135G.9 EDUCATION AND ORIENTATION
18 FOR BIRTH CENTER CLIENTS AND THEIR FAMILIES.

19 1. The clients and their families shall be fully informed
20 of the policies and procedures of the licensed birth center,
21 including, but not limited to, policies and procedures on:

22 a. The selection of clients.

23 b. The expectation of self-help and family/client rela-
24 tionships.

25 c. The qualifications of the clinical staff.

26 d. The transfer to a licensed hospital.

27 e. The philosophy of childbirth care and the scope of ser-
28 vices.

29 f. The customary length of stay after delivery.

30 2. The clients shall be prepared for childbirth and child-
31 bearing by education in:

32 a. The course of pregnancy and normal changes occurring
33 during pregnancy.

34 b. The need for prenatal care.

35 c. Nutrition.

- 1 d. The effects of smoking and substance abuse.
- 2 e. Labor and delivery.
- 3 f. The care of the newborn.

4 Sec. 10. NEW SECTION. 135G.10 PRENATAL CARE OF BIRTH
5 CENTER CLIENTS.

6 1. A licensed birth center shall ensure that its clients
7 have adequate prenatal care, as defined by the department, and
8 shall ensure that serological tests are administered as re-
9 quired by this chapter.

10 2. Records of prenatal care shall be maintained for each
11 client and shall be available during labor and delivery.

12 Sec. 11. NEW SECTION. 135G.11 PERFORMANCE OF LABORATORY
13 AND SURGICAL SERVICES -- USE OF ANESTHETIC AND CHEMICAL
14 AGENTS.

15 1. LABORATORY SERVICES. A licensed birth center may col-
16 lect specimens for those tests that are required under
17 protocol. A licensed birth center staff member may perform
18 simple laboratory tests, as defined by administrative rule.

19 2. SURGICAL SERVICES. Surgical procedures shall be li-
20 mited to those normally performed during uncomplicated child-
21 births, such as episiotomies and repairs and shall not include
22 operative obstetrics or caesarean sections.

23 3. ADMINISTRATION OF ANALGESIA AND ANESTHESIA. General
24 and conduction anesthesia may not be administered at a li-
25 censed birth center. Systemic analgesia may be administered,
26 and local anesthesia for pudendal block and episiotomy repair
27 may be performed if procedures are outlined by the clinical
28 staff and performed by personnel with statutory authority to
29 do so.

30 4. INTRAPARTAL USE OF CHEMICAL AGENTS. Labor may not be
31 inhibited, stimulated, or augmented with chemical agents
32 during the first or second stage of labor unless prescribed by
33 personnel with statutory authority to do so and unless in
34 connection with and prior to emergency transport.

35 Sec. 12. NEW SECTION. 135G.12 AGREEMENTS WITH CONSUL-

1 TANTS FOR ADVICE OR SERVICES -- MAINTENANCE.

2 1. A licensed birth center shall maintain in writing a
3 consultation agreement, signed within the current license
4 year, with each consultant who has agreed to provide advice
5 and services to the birth center as requested, which shall
6 include emergency backup services.

7 2. Consultation may be provided on-site or by telecom-
8 munication as required by clinical and geographic conditions.

9 3. The consultation agreement shall provide for a minimum
10 of two prenatal visits between each patient and a consultant.

11 Sec. 13. NEW SECTION. 135G.13 TRANSFER AND TRANSPORT OF
12 CLIENTS TO HOSPITALS.

13 1. If complications arise during labor, the client shall
14 be transferred to a hospital.

15 2. Each licensed birth center shall make arrangements with
16 a local ambulance service for the transport of emergency pa-
17 tients to a hospital. Such arrangements shall be documented
18 in the policy and procedures manual of the birth center if the
19 birth center does not own or operate a licensed ambulance.
20 The policy and procedures manual shall also contain specific
21 protocols for the transfer of any patient to a licensed hos-
22 pital.

23 3. A licensed birth center shall identify
24 neonatal/specific transportation services, including ground
25 and air ambulances, list particular qualifications of such
26 services, and have the telephone numbers for access to these
27 services clearly listed and immediately available.

28 4. Annual assessments of the transportation services and
29 transfer protocols shall be made and documented and kept on
30 file at the licensed birth center.

31 Sec. 14. NEW SECTION. 135G.14 POSTPARTUM CARE FOR BIRTH
32 CENTER CLIENTS AND INFANTS.

33 1. A mother and her infant shall be dismissed from the
34 licensed birth center within twenty-four hours after the birth
35 of the infant except in unusual circumstances as defined by

1 administrative rule. If a mother or infant is retained at the
2 birth center for more than twenty-four hours after the birth,
3 a report shall be filed with the department within forty-eight
4 hours of the birth describing the circumstances and the
5 reasons for the decision.

6 2. A prophylactic shall be instilled in the eyes of each
7 newborn in accordance with section 140.13.

8 3. Postpartum evaluation and follow-up care shall be pro-
9 vided, which shall include:

10 a. Physical examination of the infant.

11 b. Metabolic screening tests required by statute or ad-
12 ministrative rule.

13 c. Referral to sources for pediatric care.

14 d. Maternal postpartum assessment.

15 e. Instruction in child care, including immunization.

16 f. Family planning services.

17 g. Referral to a licensed hospital.

18 Sec. 15. NEW SECTION. 135G.15 CLINICAL RECORDS.

19 1. Clinical records shall contain information prescribed
20 by rule, including, but not limited to:

21 a. Identifying information.

22 b. Risk assessments.

23 c. Information relating to prenatal visits.

24 d. Information relating to course of labor and intrapartum
25 care.

26 e. Information relating to consultation, referral, and
27 transport to a hospital.

28 f. Newborn assessment, apgar score, treatments as
29 required, and follow-up.

30 g. Postpartum follow-up.

31 2. Clinical records shall be immediately available at the
32 birth center:

33 a. At the time of admission.

34 b. When transfer of care is necessary.

35 c. For audit by licensure personnel.

1 3. a. Clinical records shall be kept confidential in ac-
2 cordance with chapter 22.

3 b. A client's clinical records are considered confidential
4 documents and shall be open to inspection only under the fol-
5 lowing conditions:

6 (1) If a consent to release information has been signed by
7 the client; or

8 (2) The review is made by the department for a licensure
9 survey or complaint investigation.

10 4. a. Clinical records shall be audited periodically, but
11 no less frequently than every three months, to evaluate the
12 process and outcome of care.

13 b. Statistics on maternal and perinatal morbidity and
14 mortality, maternal risk, consultant referrals, and transfers
15 of care shall be analyzed at least semiannually.

16 c. The governing body shall examine the results of the
17 record audits and statistical analyses and shall make such
18 reports available for inspection by the public and licensing
19 authorities.

20 Sec. 16. NEW SECTION. 135G.16 INSPECTIONS AND INVESTIGA-
21 TIONS -- INSPECTION FEES.

22 1. The department shall make or cause to be made such
23 inspections and investigations as the department deems
24 necessary.

25 2. Each licensed birth center shall pay to the department,
26 at the time of inspection, an inspection fee established by
27 administrative rule, in an amount to cover the cost of the
28 inspection. The fees collected shall be deposited into the
29 general fund of the state.

30 3. The department shall coordinate all periodic
31 inspections for licensure made by the department to ensure
32 that the cost to the birth center of such inspections and the
33 disruption of services by such inspections is minimized.

34 Sec. 17. NEW SECTION. 135G.17 INSPECTION REPORTS.

35 1. Each licensed birth center shall maintain as public in-

1 formation, available upon request, records of all inspection
2 reports pertaining to that birth center which has been filed
3 with, or issued by, any governmental agency. Copies of such
4 reports shall be retained in the records of the birth center
5 for no less than five years from the date the reports are
6 filed and issued.

7 2. Any record, report, or document which, by state or
8 federal law or regulation, is deemed confidential shall not be
9 distributed or made available for purposes of compliance with
10 this section unless or until such confidential status expires,
11 except as pursuant to section 135G.15.

12 3. A licensed birth center shall, upon the request of any
13 person who has completed a written application with intent to
14 be admitted to such birth center or any person who is a
15 patient of such birth center, or any relative, spouse, or
16 guardian of any such person, furnish to the requestor a copy
17 of the last inspection report issued by the department or an
18 accrediting organization, whichever is most recent, pertaining
19 to the licensed birth center, as provided in subsection 1,
20 provided the person requesting such report agrees to pay a
21 reasonable charge to cover copying costs.

22 Sec. 18. NEW SECTION. 135G.18 BIRTH AND DEATH RECORDS --
23 REPORTS.

24 1. A completed certificate of birth shall be filed pur-
25 suant to section 144.13, and the registration fee pursuant to
26 section 144.13A shall be charged and remitted.

27 2. Each newborn death and stillbirth shall be reported
28 pursuant to section 144.29.

29 3. The licensee shall comply with all requirements of this
30 chapter and administrative rules.

31 4. A report shall be submitted annually to the department
32 by the licensee. The contents of the report shall be
33 prescribed by administrative rule.

34 Sec. 19. NEW SECTION. 135G.19 ADMINISTRATIVE PENALTIES -
35 -EMERGENCY ORDERS -- MORATORIUM ON ADMISSIONS.

1 1. a. The department may deny, revoke, or suspend a
2 license, or impose an administrative fine not to exceed five
3 hundred dollars per violation per day, for the violation of
4 this chapter or any administrative rule. Each day of
5 violation constitutes a separate violation and is subject to a
6 separate fine.

7 b. In determining the amount of the fine to be levied for
8 a violation, as provided in paragraph "a", the following fac-
9 tors shall be considered:

10 (1) The severity of the violation, including the
11 probability that death or serious harm to the health or safety
12 of any person will result or has resulted; the severity of the
13 actual or potential harm; and the extent to which the
14 provisions of this chapter and administrative rules were
15 violated.

16 (2) Actions taken by the licensee to correct the viola-
17 tions or to remedy complaints.

18 (3) Any previous violations by the licensee.

19 c. All amounts collected pursuant to this section shall be
20 deposited into the general fund of the state.

21 2. The department may issue an emergency order immediately
22 suspending or revoking a license when the department
23 determines that any condition in the licensed birth center
24 presents a clear and present danger to the public health and
25 safety.

26 3. The department may impose an immediate moratorium on
27 elective admissions to any licensed birth center, building or
28 portion thereof, or service when the department determines
29 that any condition in the birth center presents a threat to
30 the public health or safety.

31 Sec. 20. NEW SECTION. 135G.20 INJUNCTIVE RELIEF.

32 Notwithstanding the existence or pursuit of any other
33 remedy, the department may maintain an action in the name of
34 the state for injunction or other process to enforce this
35 chapter and administrative rules.

HOUSE FILE 328
FISCAL NOTE

REQUESTED BY REPRESENTATIVE FEY

In compliance with a written request received March 3, 1986, a fiscal note for **HOUSE FILE 328** is hereby submitted pursuant to Joint Rule 17. Data used in developing this fiscal note are available from the Legislative Fiscal Bureau to members of the Legislature upon request.

House File 328 requires the licensure of birthing centers which are to be inspected using standards established by the Department of Inspections and Appeals. Additionally, provisions are specified regarding inspections, governing bodies, and maintaining of records. Penalties for noncompliance of birthing centers as described in the proposed law are included in the bill.

ASSUMPTIONS: The fiscal impact of House File 328 is based on the following assumptions.

1. Presently there is only one birthing center in Iowa. It is unknown if whether additional centers will open.
2. It is unknown whether additional centers will be established in the future.

FISCAL IMPACT: Based on the above assumptions, House File 328 would cost the Department of Inspections and Appeals approximately \$5,600 - \$600 for site inspection and \$5,000 for development of standards and rules.

Source: Department of Inspections and Appeals

(LSB 2444H.2, JEM)

FILED MARCH 4, 1987

BY DENNIS PROUTY, FISCAL DIRECTOR

HOUSE FILE 328

H-3123

- 1 Amend House File 328 as follows:
2 1. Page 14, by inserting after line 6, the
3 following:
4 "Sec. _____. There is appropriated from the general
5 fund of the state to the department of inspections and
6 appeals for the fiscal year beginning July 1, 1987 and
7 ending June 30, 1988, thirty-eight thousand nine
8 hundred (38,900) dollars, or so much thereof as is
9 necessary, for salaries, support, maintenance, and
10 expenses necessary for inspections and licensure of
11 birth centers."
12 2. Title page, by striking line 2 and inserting
13 the following: ", providing penalties, and making an
14 appropriation."

H-3123 FILED FEBRUARY 26, 1987 BY VAN CAMP of Scott
Adopted 3/3/87 (p. 507)

HOUSE FILE 328

H-3129

- 1 Amend House File 328 as follows:
2 1. Page 1, line 22, by striking the figure "150A"
3 and inserting the following: "150A,".
4 2. Page 1, line 23, by inserting after the word
5 "center" the following: "and clients of the birth
6 center,".
7 3. Page 5, line 25, by inserting after the word
8 "disciplines." the following: "All services provided
9 to and procedures performed on a client of a birth
10 center, which are required by statute to be performed
11 by a licensed or certified person, shall be performed
12 only by a person so licensed or certified."
13 4. Page 8, by striking lines 28 and 29, and
14 inserting the following: "staff."
15 5. Page 9, line 5, by inserting after the word
16 "center" the following: "and clients of the birth
17 center,".

H-3129 FILED FEBRUARY 27, 1987 BY HAMMOND of Story
Adopted 3/3/87 (p. 506)

HOUSE FILE 328

H-3140

- 1 Amend amendment H-3123 to House File 328 as
2 follows:
3 1. By striking lines 7 and 8 and inserting the
4 following: "ending June 30, 1988, five thousand
5 (5,000) dollars, or so much thereof as is necessary,
6 for salaries, support, maintenance, and".

H-3140 FILED MARCH 3, 1987 BY VAN CAMP of Scott
ADOPTED BY UNANIMOUS CONSENT *(p. 507)*

HUMAN RESOURCES: Hannon, Chair; Lind and Murphy

HOUSE FILE 328

BY COMMITTEE ON HUMAN RESOURCES

(As Amended and Passed by the House March 3, 1987)

Re Passed House, Date 4/27/87 (y. 1666) Passed Senate, Date 4-14-87 (y. 1282)

Vote: Ayes 89 Nays 8 Vote: Ayes 41 Nays 8

Approved June 4, 1987

A BILL FOR

- 1 An Act relating to the licensure and regulation of birth centers
- 2 and providing penalties.

3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

HOUSE FILE 328

S-3466

- 1 Amend House File 328 as amended, passed, and
- 2 reprinted by the House as follows:
- 3 1. Page 14, line 9, by striking the word "day"
- 4 and inserting the following: "week".

S-3466

Filed April 8, 1987
Adopted 4/14/87 (y. 1282)

BY COMMITTEE ON HUMAN RESOURCES
BEVERLY A. HANNON, Chairperson

HOUSE FILE 328

S-3495

- 1 Amend House File 328 as amended, passed, and
- 2 reprinted by the House as follows:
- 3 1. Page 4, line 22, by inserting after the word
- 4 "department" the following: "which shall be equal to
- 5 the actual costs incurred by the department plus ten
- 6 percent".

S-3495

Filed April 9, 1987
Lost 4/14/87 (y. 1282)

BY JIM LIND

SENATE AMENDMENT TO HOUSE FILE 328

H-3840

- 1 Amend House File 328 as amended, passed, and
- 2 reprinted by the House as follows:
- 3 1. Page 14, line 9, by striking the word "day"
- 4 and inserting the following: "week".

H-3840 FILED APRIL 16, 1987 RECEIVED FROM THE SENATE

House concurred 4/27/87 (y. 1666)

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2 OF BIRTH CENTERS -- LEGISLATIVE INTENT.

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21 3. "Consultant" means a physician licensed under chapter
22 148, 150, or 150A, who agrees to provide medical and
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24 of the birth center, and who either:

25 a. Is certified or eligible for certification by the
26 American board of obstetrics and gynecology, or

27 b. Has hospital obstetrical privileges.

28 4. "Department" means the department of inspections and
29 appeals.

30 5. "Governing body" means any individual, group, corpora-
31 tion, or institution which is responsible for the overall
32 operation and maintenance of a birth center.

33 6. "Political subdivision" means the state or any county,
34 municipality, or other entity or subdivision of government.

35 7. "Licensed birth center" means a birth center licensed

1 in accordance with section 135G.4.

2 8. "Low-risk pregnancy" means a pregnancy which is ex-
3 pected to result in an uncomplicated birth, as determined
4 through risk criteria developed by departmental rule, and
5 which is accompanied by adequate prenatal care.

6 9. "Person" means person as defined in section 4.1, sub-
7 section 13.

8 10. "Premises" means those buildings, beds, and facilities
9 located at the main address of the licensee and all other
10 buildings, beds, and facilities for the provision of maternity
11 care located in such reasonable proximity to the main address
12 of the licensee as to appear to the public to be under the
13 dominion and control of the licensee.

14 Sec. 3. NEW SECTION. 135G.3 LICENSURE REQUIREMENT FOR
15 BIRTH CENTERS.

16 1. A person or governmental unit shall not establish, con-
17 duct, or maintain a birth center in this state without first
18 obtaining a license under section 135G.4.

19 2. A person shall not use or advertise to the public, in
20 any way or by any medium whatsoever, any facility as a birth
21 center unless such facility has first secured a license under
22 section 135G.4.

23 Sec. 4. NEW SECTION. 135G.4 LICENSURE -- ISSUANCE,
24 RENEWAL, DENIAL, SUSPENSION, REVOCATION -- FEES.

25 1. a. The department shall not issue a birth center
26 license to any applicant until:

27 (1) The department has ascertained that the staff and
28 equipment of the birth center is adequate to provide the care
29 and services required of a birth center.

30 (2) The birth center has been inspected by the state fire
31 marshal or a deputy appointed by the fire marshal for that
32 purpose, who may be a member of a municipal fire department,
33 and the department has received either a certificate of
34 compliance or a provisional certificate of compliance by the
35 birth center with the fire-hazard and fire-safety rules and

1 standards of the department as promulgated by the fire
2 marshal. The state fire marshal shall adopt rules relating to
3 fire-hazard and fire safety standards pursuant to chapter 17A
4 which shall not exceed the provision of smoke alarms, fire
5 extinguishers, sprinkler systems, and fire escape routes and
6 necessary rules which parallel state or local building code
7 rules.

8 The rules and standards promulgated by the fire marshal
9 shall be substantially in keeping with the latest generally
10 recognized safety criteria for the birth centers covered, of
11 which the applicable criteria recommended and published from
12 time to time by the national fire protection association shall
13 be prima facie evidence.

14 The state fire marshal or the fire marshal's deputy may
15 issue successive provisional certificates of compliance for
16 periods of one year each to a birth center which is in
17 substantial compliance with the applicable fire-hazard and
18 fire-safety rules and standards, upon satisfactory evidence of
19 an intent, in good faith, by the owner or operator of the
20 birth center to correct the deficiencies noted upon inspection
21 within a reasonable period of time as determined by the state
22 fire marshal or the fire marshal's deputy. Renewal of a
23 provisional certificate shall be based on a showing of
24 substantial progress in eliminating deficiencies noted upon
25 the last previous inspection of the birth center without the
26 appearance of additional deficiencies other than those arising
27 from changes in the fire-hazard and fire-safety rules,
28 regulations and standards which have occurred since the last
29 previous inspection, except that substantial progress toward
30 achievement of a good-faith intent by the owner or operator to
31 replace the entire facility within a reasonable period of
32 time, as determined by the state fire marshal or the fire
33 marshal's deputy, may be accepted as a showing of substantial
34 progress in eliminating deficiencies, for the purposes of this
35 section.

1 b. A provisional license may be issued to any birth center
2 that is in substantial compliance with this chapter and with
3 the rules adopted by the department. A provisional license
4 may be granted for a period of no more than one year from the
5 effective date of rules adopted by the department, shall
6 expire automatically at the end of its term, and shall not be
7 renewed.

8 c. A license, unless sooner suspended or revoked, auto-
9 matically expires one year from its date of issuance and is
10 renewable upon application for renewal and payment of the fee
11 prescribed, provided the applicant and the birth center meet
12 the requirements established under this chapter and by rules
13 adopted by the department. A complete application for renewal
14 of a license shall be made ninety days prior to expiration of
15 the license on forms provided by the department.

16 2. An application for a license, or renewal thereof, shall
17 be made to the department upon forms provided by the
18 department and shall contain information the department may
19 require.

20 3. a. Each application for a birth center license, or re-
21 newal thereof, shall be accompanied by a license fee. Fees
22 shall be established by rule of the department. Such fees
23 shall be deposited in the general fund of the state.

24 b. The fees established shall be based on actual costs in-
25 curred by the department in the administration of its duties
26 under this chapter.

27 4. Each license is valid only for the person or govern-
28 mental unit to whom or which the license is issued and is not
29 subject to sale, assignment, or other transfer, voluntary, or
30 involuntary; and is not valid for any premises other than
31 those for which the license was originally issued.

32 5. Each license shall be posted in a conspicuous place on
33 the licensed premises.

34 6. The department may deny, suspend, or revoke a license
35 when the department finds that there has been a substantial

1 failure to comply with the requirements established under this
2 chapter or by administrative rule.

3 Sec. 5. NEW SECTION. 135G.5 ADMINISTRATION OF BIRTH
4 CENTER.

5 1. Each licensed birth center shall have a governing body
6 which is responsible for the overall operation and maintenance
7 of the birth center.

8 a. The governing body shall develop a table of
9 organization which shows the structure of the birth center and
10 identifies the governing body, the birth center director, the
11 clinical director, the clinical staff, the medical consultant,
12 and other administrative positions.

13 b. The governing body shall develop and make available to
14 staff, clinicians, consultants, and licensing authorities, a
15 manual which documents policies, procedures, and protocols,
16 including the roles and responsibilities of all personnel.

17 2. There shall be an adequate number of licensed personnel
18 as determined by departmental rule to provide clinical
19 services needed by mothers and newborns and a sufficient
20 number of qualified personnel as determined by departmental
21 rule to provide services for families and to maintain the
22 birth center.

23 3. All clinical staff members and consultants shall hold
24 current and valid licenses from this state to practice their
25 respective disciplines. All services provided to and
26 procedures performed on a client of a birth center, which are
27 required by statute to be performed by a licensed or certified
28 person, shall be performed only by a person so licensed or
29 certified.

30 4. The governing body shall adopt bylaws for the birth
31 center which shall include recommendations for clinical staff
32 or consultation appointments, delineation of clinical
33 privileges, and the organization of the clinical staff.

34 Sec. 6. NEW SECTION. 135G.6 BIRTH CENTER AND EQUIPMENT -
35 -REQUIREMENTS.

1 1. A licensed birth center shall be so designed to assure
2 adequate provision for birthing rooms, bath and toilet fa-
3 cilities, storage areas for supplies and equipment, examina-
4 tion areas, and reception or family areas. Handwashing
5 facilities shall be in, or immediately adjacent to, all
6 examining areas and birthing rooms.

7 2. a. A licensed birth center shall be equipped with
8 those items needed to provide low-risk maternity care and
9 readily available equipment to initiate emergency procedures
10 in life-threatening events to mother and baby, as defined by
11 departmental rule.

12 b. Provisions shall be made, on or off the premises, for
13 laundry, sterilization of supplies and equipment, laboratory
14 examinations, and light snacks. If a food service is pro-
15 vided, special requirements shall be met as defined by de-
16 partmental rule.

17 3. a. A licensed birth center shall be maintained in a
18 safe, clean, and orderly manner.

19 b. The governing body shall ensure that there is compli-
20 ance with fire safety provisions required by the state.

21 Sec. 7. NEW SECTION. 135G.7 MINIMUM STANDARDS FOR BIRTH
22 CENTERS -- RULES AND ENFORCEMENT.

23 The department shall adopt rules pursuant to chapter 17A to
24 administer this chapter. The rules shall be subject to
25 approval by the board of health prior to adoption by the
26 department of inspections and appeals. The department shall
27 adopt and enforce rules setting minimum standards for birth
28 centers. However, the standards shall parallel and shall not
29 exceed standards adopted by the maternity center association,
30 and state and local building codes where applicable,
31 including:

32 1. Sufficient numbers and qualified types of personnel and
33 occupational disciplines are available at all times to provide
34 necessary and adequate patient care and safety.

35 2. Infection control, housekeeping, sanitary conditions,

1 disaster plan, and medical record procedures which adequately
2 protect patient care and provide safety are established and
3 implemented.

4 3. Licensed birth centers are established, organized, and
5 operated consistent with established programmatic standards in
6 accordance with the maternity center association.

7 Sec. 8. NEW SECTION. 135G.8 SELECTION OF CLIENTS -- IN-
8 FORMED CONSENT.

9 1. a. A licensed birth center may accept only those pa-
10 tients who are expected to have normal pregnancies, labors,
11 and deliveries.

12 b. The criteria for the selection of clients and the es-
13 tablishment of risk status shall be defined by departmental
14 rule, which shall reflect risk status standards adopted by the
15 maternity center association.

16 2. a. A patient may not be accepted for care until the
17 patient has signed a client informed-consent form.

18 b. The department shall develop a client informed-consent
19 form to be used by the center to inform the client of the
20 benefits and risk related to childbirth outside a hospital.

21 Sec. 9. NEW SECTION. 135G.9 EDUCATION AND ORIENTATION
22 FOR BIRTH CENTER CLIENTS AND THEIR FAMILIES.

23 1. The clients and their families shall be fully informed
24 of the policies and procedures of the licensed birth center,
25 including, but not limited to, policies and procedures on:

- 26 a. The selection of clients.
- 27 b. The expectation of self-help and family/client rela-
28 tionships.
- 29 c. The qualifications of the clinical staff.
- 30 d. The transfer to a licensed hospital.
- 31 e. The philosophy of childbirth care and the scope of ser-
32 vices.
- 33 f. The customary length of stay after delivery.

34 2. The clients shall be prepared for childbirth and child-
35 bearing by education in:

- 1 a. The course of pregnancy and normal changes occurring
- 2 during pregnancy.
- 3 b. The need for prenatal care.
- 4 c. Nutrition.
- 5 d. The effects of smoking and substance abuse.
- 6 e. Labor and delivery.
- 7 f. The care of the newborn.

8 Sec. 10. NEW SECTION. 135G.10 PRENATAL CARE OF BIRTH
9 CENTER CLIENTS.

10 1. A licensed birth center shall ensure that its clients
11 have adequate prenatal care, as defined by the department, and
12 shall ensure that serological tests are administered as re-
13 quired by this chapter.

14 2. Records of prenatal care shall be maintained for each
15 client and shall be available during labor and delivery.

16 Sec. 11. NEW SECTION. 135G.11 PERFORMANCE OF LABORATORY
17 AND SURGICAL SERVICES -- USE OF ANESTHETIC AND CHEMICAL
18 AGENTS.

19 1. LABORATORY SERVICES. A licensed birth center may col-
20 lect specimens for those tests that are required under
21 protocol. A licensed birth center staff member may perform
22 simple laboratory tests, as defined by administrative rule.

23 2. SURGICAL SERVICES. Surgical procedures shall be li-
24 mited to those normally performed during uncomplicated child-
25 births, such as episiotomies and repairs and shall not include
26 operative obstetrics or caesarean sections.

27 3. ADMINISTRATION OF ANALGESIA AND ANESTHESIA. General
28 and conduction anesthesia may not be administered at a li-
29 censed birth center. Systemic analgesia may be administered,
30 and local anesthesia for pudendal block and episiotomy repair
31 may be performed if procedures are outlined by the clinical
32 staff.

33 4. INTRAPARTAL USE OF CHEMICAL AGENTS. Labor may not be
34 inhibited, stimulated, or augmented with chemical agents
35 during the first or second stage of labor unless prescribed by

1 personnel with statutory authority to do so and unless in
2 connection with and prior to emergency transport.

3 Sec. 12. NEW SECTION. 135G.12 AGREEMENTS WITH CONSUL-
4 TANTS FOR ADVICE OR SERVICES -- MAINTENANCE.

5 1. A licensed birth center shall maintain in writing a
6 consultation agreement, signed within the current license
7 year, with each consultant who has agreed to provide advice
8 and services to the birth center and clients of the birth
9 center, as requested, which shall include emergency backup
10 services.

11 2. Consultation may be provided on-site or by telecom-
12 munication as required by clinical and geographic conditions.

13 3. The consultation agreement shall provide for a minimum
14 of two prenatal visits between each patient and a consultant.

15 Sec. 13. NEW SECTION. 135G.13 TRANSFER AND TRANSPORT OF
16 CLIENTS TO HOSPITALS.

17 1. If complications arise during labor, the client shall
18 be transferred to a hospital.

19 2. Each licensed birth center shall make arrangements with
20 a local ambulance service for the transport of emergency pa-
21 tients to a hospital. Such arrangements shall be documented
22 in the policy and procedures manual of the birth center if the
23 birth center does not own or operate a licensed ambulance.
24 The policy and procedures manual shall also contain specific
25 protocols for the transfer of any patient to a licensed hos-
26 pital.

27 3. A licensed birth center shall identify
28 neonatal/specific transportation services, including ground
29 and air ambulances, list particular qualifications of such
30 services, and have the telephone numbers for access to these
31 services clearly listed and immediately available.

32 4. Annual assessments of the transportation services and
33 transfer protocols shall be made and documented and kept on
34 file at the licensed birth center.

35 Sec. 14. NEW SECTION. 135G.14 POSTPARTUM CARE FOR BIRTH

1 CENTER CLIENTS AND INFANTS.

2 1. A mother and her infant shall be dismissed from the
3 licensed birth center within twenty-four hours after the birth
4 of the infant except in unusual circumstances as defined by
5 administrative rule. If a mother or infant is retained at the
6 birth center for more than twenty-four hours after the birth,
7 a report shall be filed with the department within forty-eight
8 hours of the birth describing the circumstances and the
9 reasons for the decision.

10 2. A prophylactic shall be instilled in the eyes of each
11 newborn in accordance with section 140.13.

12 3. Postpartum evaluation and follow-up care shall be pro-
13 vided, which shall include:

14 a. Physical examination of the infant.

15 b. Metabolic screening tests required by statute or ad-
16 ministrative rule.

17 c. Referral to sources for pediatric care.

18 d. Maternal postpartum assessment.

19 e. Instruction in child care, including immunization.

20 f. Family planning services.

21 g. Referral to a licensed hospital.

22 Sec. 15. NEW SECTION. 135G.15 CLINICAL RECORDS.

23 1. Clinical records shall contain information prescribed
24 by rule, including, but not limited to:

25 a. Identifying information.

26 b. Risk assessments.

27 c. Information relating to prenatal visits.

28 d. Information relating to course of labor and intrapartum
29 care.

30 e. Information relating to consultation, referral, and
31 transport to a hospital.

32 f. Newborn assessment, apgar score, treatments as
33 required, and follow-up.

34 g. Postpartum follow-up.

35 2. Clinical records shall be immediately available at the

1 birth center:

- 2 a. At the time of admission.
- 3 b. When transfer of care is necessary.
- 4 c. For audit by licensure personnel.

5 3. a. Clinical records shall be kept confidential in ac-
6 cordance with chapter 22.

7 b. A client's clinical records are considered confidential
8 documents and shall be open to inspection only under the fol-
9 lowing conditions:

10 (1) If a consent to release information has been signed by
11 the client; or

12 (2) The review is made by the department for a licensure
13 survey or complaint investigation.

14 4. a. Clinical records shall be audited periodically, but
15 no less frequently than every three months, to evaluate the
16 process and outcome of care.

17 b. Statistics on maternal and perinatal morbidity and
18 mortality, maternal risk, consultant referrals, and transfers
19 of care shall be analyzed at least semiannually.

20 c. The governing body shall examine the results of the
21 record audits and statistical analyses and shall make such
22 reports available for inspection by the public and licensing
23 authorities.

24 Sec. 16. NEW SECTION. 135G.16 INSPECTIONS AND INVESTIGA-
25 TIONS -- INSPECTION FEES.

26 1. The department shall make or cause to be made such
27 inspections and investigations as the department deems
28 necessary.

29 2. Each licensed birth center shall pay to the department,
30 at the time of inspection, an inspection fee established by
31 administrative rule, in an amount to cover the cost of the
32 inspection. The fees collected shall be deposited into the
33 general fund of the state.

34 3. The department shall coordinate all periodic
35 inspections for licensure made by the department to ensure

1 that the cost to the birth center of such inspections and the
2 disruption of services by such inspections is minimized.

3 Sec. 17. NEW SECTION. 135G.17 INSPECTION REPORTS.

4 1. Each licensed birth center shall maintain as public in-
5 formation, available upon request, records of all inspection
6 reports pertaining to that birth center which has been filed
7 with, or issued by, any governmental agency. Copies of such
8 reports shall be retained in the records of the birth center
9 for no less than five years from the date the reports are
10 filed and issued.

11 2. Any record, report, or document which, by state or
12 federal law or regulation, is deemed confidential shall not be
13 distributed or made available for purposes of compliance with
14 this section unless or until such confidential status expires,
15 except as pursuant to section 135G.15.

16 3. A licensed birth center shall, upon the request of any
17 person who has completed a written application with intent to
18 be admitted to such birth center or any person who is a
19 patient of such birth center, or any relative, spouse, or
20 guardian of any such person, furnish to the requestor a copy
21 of the last inspection report issued by the department or an
22 accrediting organization, whichever is most recent, pertaining
23 to the licensed birth center, as provided in subsection 1,
24 provided the person requesting such report agrees to pay a
25 reasonable charge to cover copying costs.

26 Sec. 18. NEW SECTION. 135G.18 BIRTH AND DEATH RECORDS --
27 REPORTS.

28 1. A completed certificate of birth shall be filed pur-
29 suant to section 144.13, and the registration fee pursuant to
30 section 144.13A shall be charged and remitted.

31 2. Each newborn death and stillbirth shall be reported
32 pursuant to section 144.29.

33 3. The licensee shall comply with all requirements of this
34 chapter and administrative rules.

35 4. A report shall be submitted annually to the department

1 by the licensee. The contents of the report shall be
2 prescribed by administrative rule.

3 Sec. 19. NEW SECTION. 135G.19 ADMINISTRATIVE PENALTIES -
4 -EMERGENCY ORDERS -- MORATORIUM ON ADMISSIONS.

5 1. a. The department may deny, revoke, or suspend a
6 license, or impose an administrative fine not to exceed five
7 hundred dollars per violation per day, for the violation of
8 this chapter or any administrative rule. Each day of
9 violation constitutes a separate violation and is subject to a
10 separate fine.

11 b. In determining the amount of the fine to be levied for
12 a violation, as provided in paragraph "a", the following fac-
13 tors shall be considered:

14 (1) The severity of the violation, including the
15 probability that death or serious harm to the health or safety
16 of any person will result or has resulted; the severity of the
17 actual or potential harm; and the extent to which the
18 provisions of this chapter and administrative rules were
19 violated.

20 (2) Actions taken by the licensee to correct the viola-
21 tions or to remedy complaints.

22 (3) Any previous violations by the licensee.

23 c. All amounts collected pursuant to this section shall be
24 deposited into the general fund of the state.

25 2. The department may issue an emergency order immediately
26 suspending or revoking a license when the department
27 determines that any condition in the licensed birth center
28 presents a clear and present danger to the public health and
29 safety.

30 3. The department may impose an immediate moratorium on
31 elective admissions to any licensed birth center, building or
32 portion thereof, or service when the department determines
33 that any condition in the birth center presents a threat to
34 the public health or safety.

35 Sec. 20. NEW SECTION. 135G.20 INJUNCTIVE RELIEF.

1 Notwithstanding the existence or pursuit of any other
2 remedy, the department may maintain an action in the name of
3 the state for injunction or other process to enforce this
4 chapter and administrative rules.

5 Sec. 21. NEW SECTION. 135G.21 ESTABLISHING, MANAGING, OR
6 OPERATING A BIRTH CENTER WITHOUT A LICENSE -- PENALTY.

7 Any person who establishes, conducts, manages, or operates
8 any birth center without a license is guilty of a simple
9 misdemeanor. Each day of continuing violation after
10 conviction shall be considered a separate offense.

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HOUSE FILE 328

AN ACT
RELATING TO THE LICENSURE AND REGULATION OF BIRTH CENTERS
AND PROVIDING PENALTIES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. NEW SECTION. 135G.1 LICENSURE AND REGULATION
OF BIRTH CENTERS -- LEGISLATIVE INTENT.

It is the intent of the general assembly to provide for the protection of public health and safety in the establishment, construction, maintenance, and operation of birth centers by providing for licensure of birth centers and for the development, establishment, and enforcement of minimum standards with respect to birth centers.

Sec. 2. NEW SECTION. 135G.2 DEFINITIONS.

As used in this chapter, unless the context otherwise requires:

1. "Birth center" means any facility, institution, or place, which is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.
2. "Clinical staff" means individuals employed full time or part time by a birth center who are licensed or certified to provide care at childbirth, which includes the clinical director.
3. "Consultant" means a physician licensed under chapter 148, 150, or 150A, who agrees to provide medical and obstetrical advice and services to a birth center and clients of the birth center, and who either:
 - a. Is certified or eligible for certification by the American board of obstetrics and gynecology, or
 - b. Has hospital obstetrical privileges.

4. "Department" means the department of inspections and appeals.

5. "Governing body" means any individual, group, corporation, or institution which is responsible for the overall operation and maintenance of a birth center.

6. "Political subdivision" means the state or any county, municipality, or other entity or subdivision of government.

7. "Licensed birth center" means a birth center licensed in accordance with section 135G.4.

8. "Low-risk pregnancy" means a pregnancy which is expected to result in an uncomplicated birth, as determined through risk criteria developed by departmental rule, and which is accompanied by adequate prenatal care.

9. "Person" means person as defined in section 4.1, subsection 13.

10. "Premises" means those buildings, beds, and facilities located at the main address of the licensee and all other buildings, beds, and facilities for the provision of maternity care located in such reasonable proximity to the main address of the licensee as to appear to the public to be under the dominion and control of the licensee.

Sec. 3. NEW SECTION. 135G.3 LICENSURE REQUIREMENT FOR
BIRTH CENTERS.

1. A person or governmental unit shall not establish, conduct, or maintain a birth center in this state without first obtaining a license under section 135G.4.

2. A person shall not use or advertise to the public, in any way or by any medium whatsoever, any facility as a birth center unless such facility has first secured a license under section 135G.4.

Sec. 4. NEW SECTION. 135G.4 LICENSURE -- ISSUANCE,
RENEWAL, DENIAL, SUSPENSION, REVOCATION -- FEES.

1. a. The department shall not issue a birth center license to any applicant until:

(1) The department has ascertained that the staff and equipment of the birth center is adequate to provide the care and services required of a birth center.

(2) The birth center has been inspected by the state fire marshal or a deputy appointed by the fire marshal for that purpose, who may be a member of a municipal fire department, and the department has received either a certificate of compliance or a provisional certificate of compliance by the birth center with the fire-hazard and fire-safety rules and standards of the department as promulgated by the fire marshal. The state fire marshal shall adopt rules relating to fire-hazard and fire-safety standards pursuant to chapter 17A which shall not exceed the provision of smoke alarms, fire extinguishers, sprinkler systems, and fire escape routes and necessary rules which parallel state or local building code rules.

The rules and standards promulgated by the fire marshal shall be substantially in keeping with the latest generally recognized safety criteria for the birth centers covered, of which the applicable criteria recommended and published from time to time by the national fire protection association shall be prima facie evidence.

The state fire marshal or the fire marshal's deputy may issue successive provisional certificates of compliance for periods of one year each to a birth center which is in substantial compliance with the applicable fire-hazard and fire-safety rules and standards, upon satisfactory evidence of an intent, in good faith, by the owner or operator of the birth center to correct the deficiencies noted upon inspection within a reasonable period of time as determined by the state fire marshal or the fire marshal's deputy. Renewal of a provisional certificate shall be based on a showing of substantial progress in eliminating deficiencies noted upon the last previous inspection of the birth center without the appearance of additional deficiencies other than those arising from changes in the fire-hazard and fire-safety rules, regulations and standards which have occurred since the last previous inspection, except that substantial progress toward achievement of a good-faith intent by the owner or operator to

replace the entire facility within a reasonable period of time, as determined by the state fire marshal or the fire marshal's deputy, may be accepted as a showing of substantial progress in eliminating deficiencies, for the purposes of this section.

b. A provisional license may be issued to any birth center that is in substantial compliance with this chapter and with the rules adopted by the department. A provisional license may be granted for a period of no more than one year from the effective date of rules adopted by the department, shall expire automatically at the end of its term, and shall not be renewed.

c. A license, unless sooner suspended or revoked, automatically expires one year from its date of issuance and is renewable upon application for renewal and payment of the fee prescribed, provided the applicant and the birth center meet the requirements established under this chapter and by rules adopted by the department. A complete application for renewal of a license shall be made ninety days prior to expiration of the license on forms provided by the department.

2. An application for a license, or renewal thereof, shall be made to the department upon forms provided by the department and shall contain information the department may require.

3. a. Each application for a birth center license, or renewal thereof, shall be accompanied by a license fee. Fees shall be established by rule of the department. Such fees shall be deposited in the general fund of the state.

b. The fees established shall be based on actual costs incurred by the department in the administration of its duties under this chapter.

4. Each license is valid only for the person or governmental unit to whom or which the license is issued and is not subject to sale, assignment, or other transfer, voluntary, or involuntary; and is not valid for any premises other than those for which the license was originally issued.

5. Each license shall be posted in a conspicuous place on the licensed premises.

6. The department may deny, suspend, or revoke a license when the department finds that there has been a substantial failure to comply with the requirements established under this chapter or by administrative rule.

Sec. 5. NEW SECTION. 135G.5 ADMINISTRATION OF BIRTH CENTER.

1. Each licensed birth center shall have a governing body which is responsible for the overall operation and maintenance of the birth center.

a. The governing body shall develop a table of organization which shows the structure of the birth center and identifies the governing body, the birth center director, the clinical director, the clinical staff, the medical consultant, and other administrative positions.

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 as determined by departmental rule to provide clinical services needed by mothers and newborns and a sufficient number of qualified personnel as determined by departmental rule to provide services for families and to maintain the birth center.

3. All clinical staff members and consultants shall hold current and valid licenses from this state to practice their respective disciplines. All services provided to and procedures performed on a client of a birth center, which are required by statute to be performed by a licensed or certified person, shall be performed only by a person so licensed or certified.

4. The governing body shall adopt bylaws for the birth center which shall include recommendations for clinical staff or consultation appointments, delineation of clinical privileges, and the organization of the clinical staff.

Sec. 6. NEW SECTION. 135G.6 BIRTH CENTER AND EQUIPMENT -- REQUIREMENTS.

1. A licensed birth center shall be so designed to assure adequate provision for birthing rooms, bath and toilet facilities, storage areas for supplies and equipment, examination areas, and reception or family areas. Handwashing facilities shall be in, or immediately adjacent to, all examining areas and birthing rooms.

2. a. A licensed birth center shall be equipped with those items needed to provide low-risk maternity care and readily available equipment to initiate emergency procedures in life-threatening events to mother and baby, as defined by departmental rule.

b. Provisions shall be made, on or off the premises, for laundry, sterilization of supplies and equipment, laboratory examinations, and light snacks. If a food service is provided, special requirements shall be met as defined by departmental rule.

3. a. A licensed birth center shall be maintained in a safe, clean, and orderly manner.

b. The governing body shall ensure that there is compliance with fire safety provisions required by the state.

Sec. 7. NEW SECTION. 135G.7 MINIMUM STANDARDS FOR BIRTH CENTERS -- RULES AND ENFORCEMENT.

The department shall adopt rules pursuant to chapter 17A to administer this chapter. The rules shall be subject to approval by the board of health prior to adoption by the department of inspections and appeals. The department shall adopt and enforce rules setting minimum standards for birth centers. However, the standards shall parallel and shall not exceed standards adopted by the maternity center association, and state and local building codes where applicable, including:

1. Sufficient numbers and qualified types of personnel and occupational disciplines are available at all times to provide necessary and adequate patient care and safety.

2. Infection control, housekeeping, sanitary conditions, disaster plan, and medical record procedures which adequately protect patient care and provide safety are established and implemented.

3. Licensed birth centers are established, organized, and operated consistent with established programmatic standards in accordance with the maternity center association.

Sec. 8. NEW SECTION. 135G.8 SELECTION OF CLIENTS -- INFORMED CONSENT.

1. a. A licensed 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 departmental rule, which shall reflect risk status standards adopted by the maternity center association.

2. a. A patient may not be accepted for care until the patient has signed a client informed-consent form.

b. The department shall develop a client informed-consent form to be used by the center to inform the client of the benefits and risk related to childbirth outside a hospital.

Sec. 9. NEW SECTION. 135G.9 EDUCATION AND ORIENTATION FOR BIRTH CENTER CLIENTS AND THEIR FAMILIES.

1. The clients and their families shall be fully informed of the policies and procedures of the licensed birth center, including, but not limited to, policies and procedures on:

- a. The selection of clients.
- b. The expectation of self-help and family/client relationships.
- c. The qualifications of the clinical staff.
- d. The transfer to a licensed hospital.
- 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.
- d. The effects of smoking and substance abuse.
- e. Labor and delivery.
- f. The care of the newborn.

Sec. 10. NEW SECTION. 135G.10 PRENATAL CARE OF BIRTH CENTER CLIENTS.

1. A licensed birth center shall ensure that its clients have adequate prenatal care, as defined by the department, 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.

Sec. 11. NEW SECTION. 135G.11 PERFORMANCE OF LABORATORY AND SURGICAL SERVICES -- USE OF ANESTHETIC AND CHEMICAL AGENTS.

1. LABORATORY SERVICES. A licensed birth center may collect specimens for those tests that are required under protocol. A licensed birth center staff member may perform simple laboratory tests, as defined by administrative rule.

2. SURGICAL SERVICES. Surgical procedures shall be limited to those normally performed during uncomplicated childbirths, such as episiotomies and repairs and shall not include operative obstetrics or caesarean sections.

1. ADMINISTRATION OF ANALGESIA AND ANESTHESIA. General and conduction anesthesia may not be administered at a licensed 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.

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.

Sec. 12. NEW SECTION. 135G.12 AGREEMENTS WITH CONSULTANTS FOR ADVICE OR SERVICES -- MAINTENANCE.

1. A licensed birth center shall maintain in writing a consultation agreement, signed within the current license year, with each consultant who has agreed to provide advice and services to the birth center and clients of the birth center, as requested, which shall include emergency backup services.

2. Consultation may be provided on-site or by telecommunication as required by clinical and geographic conditions.

3. The consultation agreement shall provide for a minimum of two prenatal visits between each patient and a consultant.

Sec. 13. NEW SECTION. 135G.13 TRANSFER AND TRANSPORT OF CLIENTS TO HOSPITALS.

1. If complications arise during labor, the client shall be transferred to a hospital.

2. Each licensed birth center shall make arrangements with a local ambulance service for the transport of emergency patients to a hospital. Such arrangements shall be documented in the policy and procedures manual of the birth center if the 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 licensed hospital.

3. A licensed birth center shall identify neonatal/specific transportation services, including ground and air ambulances, list particular qualifications of such services, and have the telephone numbers for access to these services clearly listed and immediately available.

4. Annual assessments of the transportation services and transfer protocols shall be made and documented and kept on file at the licensed birth center.

Sec. 14. NEW SECTION. 135G.14 POSTPARTUM CARE FOR BIRTH CENTER CLIENTS AND INFANTS.

1. A mother and her infant shall be dismissed from the licensed birth center within twenty-four hours after the birth

of the infant except in unusual circumstances as defined by administrative rule. If a mother or infant is retained at the birth center for more than twenty-four hours after the birth, a report shall be filed with the department within forty-eight hours of the birth describing the circumstances and the reasons for the decision.

2. A prophylactic shall be instilled in the eyes of each newborn in accordance with section 140.13.

3. Postpartum evaluation and follow-up care shall be provided, which shall include:

- a. Physical examination of the infant.
- b. Metabolic screening tests required by statute or administrative rule.

c. Referral to sources for pediatric care.

d. Maternal postpartum assessment.

e. Instruction in child care, including immunization.

f. Family planning services.

g. Referral to a licensed hospital.

Sec. 15. NEW SECTION. 135G.15 CLINICAL RECORDS.

1. Clinical records shall contain information prescribed by rule, including, but not limited to:

a. Identifying information.

b. Risk assessments.

c. Information relating to prenatal visits.

d. Information relating to course of labor and intrapartum care.

e. Information relating to consultation, referral, and transport to a hospital.

f. Newborn assessment, Apgar score, treatments as required, and follow-up.

g. Postpartum follow-up.

2. Clinical records shall be immediately available at the birth center:

a. At the time of admission.

b. When transfer of care is necessary.

c. For audit by licensure personnel.

3. a. Clinical records shall be kept confidential in accordance with chapter 22.

b. A client's clinical records are considered confidential documents and shall be open to inspection only under the following conditions:

(1) If a consent to release information has been signed by the client; or

(2) The review is made by the department for a licensure survey or complaint investigation.

4. a. Clinical records shall be audited periodically, but no less frequently than every three months, to evaluate the process and outcome of care.

b. Statistics on maternal and perinatal morbidity and mortality, maternal risk, consultant referrals, and transfers of care shall be analyzed at least semiannually.

c. The governing body shall examine the results of the record audits and statistical analyses and shall make such reports available for inspection by the public and licensing authorities.

Sec. 16. NEW SECTION. 135G.16 INSPECTIONS AND INVESTIGATIONS -- INSPECTION FEES.

1. The department shall make or cause to be made such inspections and investigations as the department deems necessary.

2. Each licensed birth center shall pay to the department, at the time of inspection, an inspection fee established by administrative rule, in an amount to cover the cost of the inspection. The fees collected shall be deposited into the general fund of the state.

3. The department shall coordinate all periodic inspections for licensure made by the department to ensure that the cost to the birth center of such inspections and the disruption of services by such inspections is minimized.

Sec. 17. NEW SECTION. 135G.17 INSPECTION REPORTS.

1. Each licensed birth center shall maintain as public information, available upon request, records of all inspection

reports pertaining to that birth center which has been filed with, or issued by, any governmental agency. Copies of such reports shall be retained in the records of the birth center for no less than five years from the date the reports are filed and issued.

2. Any record, report, or document which, by state or federal law or regulation, is deemed confidential shall not be distributed or made available for purposes of compliance with this section unless or until such confidential status expires, except as pursuant to section 135G.15.

3. A licensed birth center shall, upon the request of any person who has completed a written application with intent to be admitted to such birth center or any person who is a patient of such birth center, or any relative, spouse, or guardian of any such person, furnish to the requestor a copy of the last inspection report issued by the department or an accrediting organization, whichever is most recent, pertaining to the licensed birth center, as provided in subsection 1, provided the person requesting such report agrees to pay a reasonable charge to cover copying costs.

Sec. 18. NEW SECTION. 135G.18 BIRTH AND DEATH RECORDS -- REPORTS.

1. A completed certificate of birth shall be filed pursuant to section 144.13, and the registration fee pursuant to section 144.13A shall be charged and remitted.

2. Each newborn death and stillbirth shall be reported pursuant to section 144.29.

3. The licensee shall comply with all requirements of this chapter and administrative rules.

4. A report shall be submitted annually to the department by the licensee. The contents of the report shall be prescribed by administrative rule.

Sec. 19. NEW SECTION. 135G.19 ADMINISTRATIVE PENALTIES -- EMERGENCY ORDERS -- MORATORIUM ON ADMISSIONS.

1. a. The department may deny, revoke, or suspend a license, or impose an administrative fine not to exceed five

hundred dollars per violation per day, for the violation of this chapter or any administrative rule. Each day of violation constitutes a separate violation and is subject to a separate fine.

o. In determining the amount of the fine to be levied for a violation, as provided in paragraph "a", the following factors shall be considered:

(1) 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 this chapter and administrative rules were violated.

(2) Actions taken by the licensee to correct the violations or to remedy complaints.

(3) Any previous violations by the licensee.

c. All amounts collected pursuant to this section shall be deposited into the general fund of the state.

2. The department may issue an emergency order immediately suspending or revoking a license when the department determines that any condition in the licensed birth center presents a clear and present danger to the public health and safety.

3. The department may impose an immediate moratorium on elective admissions to any licensed birth center, building or portion thereof, or service when the department determines that any condition in the birth center presents a threat to the public health or safety.

Sec. 20. NEW SECTION. 135G.20 INJUNCTIVE RELIEF.

Notwithstanding the existence or pursuit of any other remedy, the department may maintain an action in the name of the state for injunction or other process to enforce this chapter and administrative rules.

Sec. 21. NEW SECTION. 135G.21 ESTABLISHING, MANAGING, OR OPERATING A BIRTH CENTER WITHOUT A LICENSE -- PENALTY.

Any person who establishes, conducts, manages, or operates any birth center without a license is guilty of a simple misdemeanor. Each week of continuing violation after conviction shall be considered a separate offense.

DONALD D. AVENSON
Speaker of the House

JO ANN ZIMMERMAN
President of the Senate

I hereby certify that this bill originated in the House and is known as House File 328, Seventy-second General Assembly.

Approved _____, 1987

JOSEPH O'HERN
Chief Clerk of the House

TERRY E. BRANSTAD
Governor

H. F. 328