

*House Bill 2049 (p. 1541) House 3/15*

SENATE FILE 2049  
BY HUTCHINS

FILED JAN 10 1990

Passed Senate, Date 1-18-90 (p. 166) Passed House, Date 3/28/90 (p. 1541)  
Vote: Ayes 35 Nays 9 Vote: Ayes 66 Nays 34

Approved April 7, 1990

*Report on Senate file 5982  
4/7/90 (p. 1660)  
44-3*

*Reference to House file (p. 1541)  
w/10 4/2*

**A BILL FOR**

1 An Act relating to the establishment of standards for the  
2 collection, processing, storage, and distribution of human  
3 blood, plasma, and blood products, and to the licensing of  
4 blood collection and plasmapheresis centers, and providing a  
5 penalty.

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

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S.F. 2049

1 Section 1. NEW SECTION. 135J.1 LICENSURE REQUIRED.

2 A person shall not establish, conduct, manage, or operate a  
3 blood collection or plasmapheresis center without obtaining a  
4 license from the Iowa department of public health. A person  
5 applying for a license to operate a blood collection or  
6 plasmapheresis center from the Iowa department of public  
7 health shall also obtain a license or be properly registered  
8 with the United States food and drug administration and shall  
9 comply with all applicable federal regulations.

10 Sec. 2. NEW SECTION. 135J.2 RULES FOR LICENSURE.

11 1. The Iowa department of public health shall adopt rules,  
12 in accordance with chapter 17A, for the licensure of blood  
13 collection and plasmapheresis centers.

14 2. The rules shall comply with the minimum operational  
15 standards and the specific requirements prescribed by the  
16 United States food and drug administration regarding blood  
17 collection and plasmapheresis centers.

18 3. The rules shall include, but are not limited to, the  
19 following:

20 a. Requirements regarding physical facilities including  
21 refrigeration, lighting, construction, and equipment.

22 b. Testing procedures for communicable diseases  
23 transmitted by blood, plasma, or blood products.

24 c. Standards for collection, processing, storage, and  
25 distribution of blood, plasma, or blood products.

26 d. Identification and screening of donors.

27 e. Qualification requirements for medical and laboratory  
28 personnel employed in a blood collection or plasmapheresis  
29 center.

30 f. Restrictions on the use of blood, plasma, or blood  
31 product donations.

32 g. A system of identifying the donor of the blood, plasma,  
33 or blood products at all times, including after the blood,  
34 plasma, or blood product has been administered to the  
35 recipient.

1 h. Establishment of a system for determining the inventory  
2 level of blood or plasma in all blood collection and  
3 plasmapheresis centers and the coordination of the  
4 distribution of blood, plasma, and blood products.

5 i. Proficiency testing.

6 j. Sanitary conditions within and surrounding the blood  
7 collection or plasmapheresis center.

8 k. A quality assurance program.

9 l. Establishment of fees for licensure and inspection.

10 4. The rules may provide for the acceptance of independent  
11 accreditation which is in conformance with the standards  
12 established by the rules.

13 Sec. 3. NEW SECTION. 135J.3 ISSUANCE, REVOCATION, OR  
14 SUSPENSION OF LICENSURE.

15 1. The Iowa department of public health shall provide  
16 application forms for licensure.

17 2. The Iowa department of public health shall issue a  
18 license to an applicant following the inspection of a blood  
19 collection or plasmapheresis center by the department or its  
20 designee, if the applicant meets all requirements for  
21 licensure.

22 3. A license is valid for one year and must be renewed on  
23 an annual basis.

24 4. The Iowa department of public health may revoke,  
25 suspend, or restrict a license at any time if the licensee is  
26 found to be in violation of this chapter or a rule adopted  
27 pursuant to this chapter.

28 Sec. 4. NEW SECTION. 135J.4 PENALTIES.

29 A person establishing, conducting, managing, or operating a  
30 blood collection or plasmapheresis center without a license is  
31 guilty of a serious misdemeanor. Each day of a continuing  
32 violation constitutes a separate offense.

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EXPLANATION

34 This bill creates a new chapter. The bill provides for the  
35 licensure of blood collection and plasmapheresis centers by

1 the Iowa department of public health. A person obtaining such  
2 a license must also be in compliance with applicable federal  
3 regulations, licensure, or registration requirements.

4 The bill also provides for the adoption of rules by the  
5 Iowa department of public health regarding licensure standards  
6 for blood collection and plasmapheresis centers.

7 The Iowa department of public health is required to provide  
8 application forms for licensure and to inspect or provide for  
9 the inspection of blood collection and plasmapheresis centers  
10 prior to issuance of a license. Licenses must be renewed  
11 annually, and the department may revoke, suspend, or restrict  
12 a license at any time if the licensee is found to be in  
13 violation of the chapter or a standard established by a rule  
14 adopted pursuant to the chapter.

15 The bill also provides that a person who establishes,  
16 conducts, manages, or operates a blood collection or  
17 plasmapheresis center without a license is guilty of a serious  
18 misdemeanor.

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SENATE FILE 2049  
FISCAL NOTE

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A fiscal note for **SENATE FILE 2049** is hereby submitted pursuant to Joint Rule 17. Data used in developing this fiscal note is available from the Legislative Fiscal Bureau to members of the Legislature upon request.

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Senate File 2049, which creates a new chapter in the Code of Iowa, establishes standards for the collection, processing, storage, and distribution of human blood, plasma, and blood products, provides for licensure of blood collection and plasmapheresis centers, and provides a penalty.

ASSUMPTIONS:

1. Each of 30 sites would be inspected twice a year.
2. One FTE position (Inspector) would be required to perform the inspections.

FISCAL EFFECT:

The estimated annual fiscal effect of Senate File 2049 is \$50,000 for salary, support, and expenses associated with the inspections.

Source: Department of Public Health

(LSB 7698xs, RRS)

FILED JANUARY 22, 1990

BY DENNIS PROUTY, FISCAL DIRECTOR

SENATE FILE 2049

H-5615

1 Amend Senate File 2049, as passed by the Senate, as  
2 follows:

3 1. By striking everything after the enacting  
4 clause and inserting the following:

5 "Section 1. NEW SECTION. 135.23. LICENSURE OF  
6 BLOOD COLLECTION, BLOOD PROCESSING, OR PLASMAPHERESIS  
7 CENTERS.

8 A person shall not establish, conduct, manage, or  
9 operate a blood collection, blood processing, or  
10 plasmapheresis center without obtaining a license from  
11 the board of pharmacy examiners. To obtain an Iowa  
12 license, a blood collection, blood processing, or  
13 plasmapheresis center shall provide verification of  
14 current licensure or proper registration with the  
15 United States food and drug administration and shall  
16 comply with all applicable federal regulations. Each  
17 blood collection, blood processing, or plasmapheresis  
18 center shall submit to the board of pharmacy  
19 examiners, on an ongoing basis, copies of the center's  
20 most recent proficiency testing results and on-site  
21 inspection reports required for licensure,  
22 registration, or accreditation with the United States  
23 food and drug administration, the American association  
24 of blood banks, the centers for disease control of the  
25 United States department of health and human services,  
26 the college of American pathologists, or the joint  
27 commission on accreditation of health care organi-  
28 zations. The purpose of the reports is to ensure  
29 compliance with the federal licensure, registration,  
30 or accreditation requirements. The department shall  
31 provide technical assistance to blood collection,  
32 blood processing, and plasmapheresis centers to ensure  
33 compliance with the requirements of the organizations  
34 named pursuant to this section."

35 2. Title page, by striking lines 1 through 5, and  
36 inserting the following: "An Act relating to the  
37 licensing of blood collection, blood processing, and  
38 plasmapheresis centers."

By COMMITTEE ON HUMAN RESOURCES  
FEY of Scott, Chairperson

H-5615 FILED MARCH 13, 1990

*Adopted as amended by 56.81A, 5713, & 5872  
3/28/90 (p. 1540)*

SENATE FILE 2049

H-5872

1 Amend the amendment, H-5615, to Senate File 2049,  
2 as passed by the Senate, as follows:

3 1. Page 1, line 34, by inserting after the word  
4 "section. the following: "The department may assess  
5 an annual licensing fee of no more than one hundred  
6 dollars."

By FEY of Scot

H-5872 FILED MARCH 26, 1990

*Adopted 3/28 (p. 1540)*

SENATE FILE 2049

H-5681

1 Amend the amendment, H-5615, to Senate File 2049,  
2 as passed by the Senate, as follows:

3 1. Page 1, line 11, by striking the words "board  
4 of pharmacy examiners" and inserting the following:  
5 "department".

6 2. Page 1, lines 18 and 19, by striking the words  
7 "board of pharmacy examiners" and inserting the  
8 following: "department".

9 3. Page 1, by inserting after line 34, the  
10 following:

11 "Notwithstanding the responsibilities of the board  
12 of pharmacy examiners relating to prescriptions for  
13 human blood, blood plasma, and blood products,  
14 established under chapter 155A, the department shall  
15 have exclusive responsibility for the licensing of  
16 blood collection, blood processing, and plasmapheresis  
17 centers."

By SPEAR of Lee

H-5681 FILED MARCH 14, 1990

*A - adopted, B - w/18 3/28 (p. 1539)*

SENATE FILE 2049

H-5713

1 Amend amendment, H-5615, to Senate File 2049, as  
2 passed by the Senate, as follows:

3 1. Page 1, by inserting after line 34, the  
4 following:

5 "Sec. \_\_\_\_ . Section 1 of this Act is repealed July  
6 1, 1991."

7 2. Page 1, line 38, by inserting after the word  
8 "centers" the following: ", and providing for a  
9 repeal".

10 3. By renumbering as necessary.

By PLASIER of Sioux

H-5713 FILED MARCH 15, 1990

*Adopted 3/28 (p. 1540)*

SENATE FILE 2049

H-5722

1 Amend the amendment, H-5615, to Senate File 2049,  
2 as passed by the Senate, as follows:

3 1. Page 1, line 5, by striking the figure  
4 "135.23" and inserting the following: "155A.39".

By FEY of Scott

H-5722 FILED MARCH 15, 1990

*w/28 3/28 (p. 1539)*

HOUSE AMENDMENT TO  
SENATE FILE 2049

S-5982

1 Amend Senate File 2049, as passed by the Senate, as  
2 follows:

3 1. By striking everything after the enacting  
4 clause and inserting the following:

5 "Section 1. NEW SECTION. 135.23 LICENSURE OF  
6 BLOOD COLLECTION, BLOOD PROCESSING, OR PLASMAPHERESIS  
7 CENTERS.

8 A person shall not establish, conduct, manage, or  
9 operate a blood collection, blood processing, or  
10 plasmapheresis center without obtaining a license from  
11 the department. To obtain an Iowa license, a blood  
12 collection, blood processing, or plasmapheresis center  
13 shall provide verification of current licensure or  
14 proper registration with the United States food and  
15 drug administration and shall comply with all  
16 applicable federal regulations. Each blood  
17 collection, blood processing, or plasmapheresis center  
18 shall submit to the department, on an ongoing basis,  
19 copies of the center's most recent proficiency testing  
20 results and on-site inspection reports required for  
21 licensure, registration, or accreditation with the  
22 United States food and drug administration, the  
23 American association of blood banks, the centers for  
24 disease control of the United States department of  
25 health and human services, the college of American  
26 pathologists, or the joint commission on accreditation  
27 of health care organizations. The purpose of the  
28 reports is to ensure compliance with the federal  
29 licensure, registration, or accreditation  
30 requirements. The department shall provide technical  
31 assistance to blood collection, blood processing, and  
32 plasmapheresis centers to ensure compliance with the  
33 requirements of the organizations named pursuant to  
34 this section. The department may assess an annual  
35 licensing fee of no more than one hundred dollars.

36 Sec. \_\_\_\_ . Section 1 of this Act is repealed July  
37 1, 1991."

38 2. Title page, by striking lines 1 through 5, and  
39 inserting the following: "An Act relating to the  
40 licensing of blood collection, blood processing, and  
41 plasmapheresis centers, and providing for a repeal."

RECEIVED FROM THE HOUSE

S-5982 FILED APRIL 6, 1990

*Senate concurred 4/7 (p. 1660)*

SENATE FILE 2049

AN ACT

RELATING TO THE LICENSING OF BLOOD COLLECTION, BLOOD PROCESSING, AND PLASMAPHERESIS CENTERS, AND PROVIDING FOR A REPEAL.

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

Section 1. NEW SECTION. 139.23 LICENSURE OF BLOOD COLLECTION, BLOOD PROCESSING, OR PLASMAPHERESIS CENTERS.

A person shall not establish, conduct, manage, or operate a blood collection, blood processing, or plasmapheresis center without obtaining a license from the department. To obtain an Iowa license, a blood collection, blood processing, or plasmapheresis center shall provide verification of current licensure or proper registration with the United States food and drug administration and shall comply with all applicable federal regulations. Each blood collection, blood processing, or plasmapheresis center shall submit to the department, on an ongoing basis, copies of the center's most recent proficiency testing results and on-site inspection reports required for licensure, registration, or accreditation with the United States food and drug administration, the American association of blood banks, the centers for disease control of the United States department of health and human services, the college of American pathologists, or the joint commission on accreditation of health care organizations. The purpose of the reports is to ensure compliance with the federal licensure, registration, or accreditation requirements. The department shall provide technical assistance to blood collection, blood processing, and plasmapheresis centers to ensure compliance with the requirements of the organizations

named pursuant to this section. The department may assess an annual licensing fee of no more than one hundred dollars.

Sec. 2. Section 1 of this Act is repealed July 1, 1991.

JO ANN ZIMMERMAN  
President of the Senate

DONALD D. AVEKSON  
Speaker of the House

I hereby certify that this bill originated in the Senate and is known as Senate File 2049, Seventy-third General Assembly.

JOHN F. DWYER  
Secretary of the Senate

Approved *April 7*, 1990

TERRY E. BRANSTAD  
Governor