

SENATE FILE 539
BY COMMITTEE ON WAYS AND MEANS

(SUCCESSOR TO SSB 355)

Passed Senate, Date 4/24/91 (p. 1445) Passed House, Date 5/6/91 (p. 2124)

Vote: Ayes 48 Nays 0 Vote: Ayes 99 Nays 0

Approved June 4, 1991

*Repassed Senate as amended
5/7/91 (p. 1702)
49-0*

A BILL FOR

1 An Act relating to the Iowa pharmacy practice Act and assessing
2 fees.

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

- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24

SF 539

1 Section 1. NEW SECTION. 155A.13A NONRESIDENT PHARMACY
2 LICENSE -- REQUIRED, RENEWAL, DISCIPLINE.

3 1. LICENSE REQUIRED. A pharmacy located outside of this
4 state which delivers, dispenses, or distributes by any method,
5 prescription drugs or devices to an ultimate user in this
6 state shall obtain a nonresident pharmacy license from the
7 board. The board shall make available an application form for
8 a nonresident pharmacy license and shall require such
9 information it deems necessary to fulfill the purposes of this
10 section. A nonresident pharmacy shall do all of the following
11 in order to obtain a nonresident pharmacy license from the
12 board:

13 a. Submit a completed application form and an application
14 fee as determined by the board.

15 b. Submit evidence of possession of a valid license,
16 permit, or registration as a pharmacy in compliance with the
17 laws of the state in which it is located, a copy of the most
18 recent inspection report resulting from an inspection
19 conducted by the regulatory or licensing agency of the state
20 in which it is located, and evidence of compliance with all
21 legal directions and requests for information issued by the
22 regulatory or licensing agency of the state in which it is
23 located.

24 c. Submit a list of the name, titles, and location of all
25 principal owners, partners, or officers of the nonresident
26 pharmacy, all pharmacists employed by the nonresident pharmacy
27 who deliver, dispense, or distribute by any method
28 prescription drugs to an ultimate user in this state, and of
29 the pharmacist in charge of the nonresident pharmacy. A
30 nonresident pharmacy shall update the list within thirty days
31 of any addition, deletion, or other change to the list.

4000 32 d. Submit evidence that the nonresident pharmacy maintains
33 records of the controlled substances delivered, dispensed, or
34 distributed to ultimate users in this state which are readily
35 retrievable and distinguishable from the nonresident

1 pharmacy's records of controlled substances delivered,
2 dispensed, or distributed to ultimate users in other states.

3 e. Submit evidence that the nonresident pharmacy provides,
4 during its regular hours of operation for at least six days
5 and for at least forty hours per week, toll-free telephone
6 service to facilitate communication between ultimate users in
7 this state and a pharmacist who has access to the ultimate
8 user's records in the nonresident pharmacy, and that the toll-
9 free number is printed on the label affixed to each container
10 of prescription drugs delivered, dispensed, or distributed in
11 this state.

12 2. LICENSE RENEWAL. A nonresident pharmacy shall renew
13 its license on or before January 1 annually. In order to
14 renew a nonresident pharmacy license, a nonresident pharmacy
15 shall submit a renewal fee as determined by the board, and
16 shall fulfill all of the requirements of subsection 1,
17 paragraphs "b" through "e". A nonresident pharmacy shall pay
18 an additional fee for late renewal for failure to renew a
19 license within thirty-one days after expiration of the
20 license.

21 3. DISCIPLINE. The board may deny, suspend, or revoke a
22 nonresident pharmacy license for any violation of this
23 chapter, chapter 203B, 204, 204A, 204B, or 205, or a rule of
24 the board.

25 Sec. 2. Section 155A.15, subsection 2, paragraph d,
26 subparagraph (4), Code 1991, is amended to read as follows:

27 (4) A manufacturer or wholesaler licensed by the board.
28 However, this chapter does not prohibit a pharmacy from
29 furnishing a prescription drug or device to a licensed health
30 care facility for storage in a secured emergency
31 pharmaceutical supplies container maintained within the
32 facility in accordance with ~~regulations~~ rules of the Iowa
33 department of ~~public-health~~ inspections and appeals.

34 Sec. 3. Section 155A.17, Code 1991, is amended to read as
35 follows:

1 155A.17 WHOLESALE DRUG LICENSE.

2 1. A person shall not establish, conduct, or maintain a
3 wholesale drug business as defined in this chapter without a
4 license. The license shall be identified as a wholesale drug
5 license.

6 2. The board shall establish standards for drug wholesaler
7 licensure and may deny, suspend, or revoke a drug wholesale
8 license for failure to meet the standards or for a violation
9 of the laws of this state, another state, or the United States
10 relating to prescription drugs or controlled substances, or
11 for a violation of this chapter, chapter 203B, 204, 204A,
12 204B, or 205, or a rule of the board.

13 3. The board shall adopt rules pursuant to chapter 17A on
14 matters pertaining to the issuance of a wholesale drug
15 license. The rules shall provide for conditions of licensure,
16 compliance standards, licensure fees, disciplinary action, and
17 other relevant matters.

18 4. This section does not apply to a manufacturer's
19 representative acting in the usual course of business or
20 employment as a manufacturer's representative.

21 Sec. 4. Section 155A.19, subsection 2, Code 1991, is
22 amended to read as follows:

23 2. A pharmacist shall report in writing to the board
24 within ten days a change of name, address, or place of
25 employment.

26 Sec. 5. Section 204.302, subsection 1, Code 1991, is
27 amended to read as follows:

28 1. Every person who manufactures, distributes, or
29 dispenses any controlled substance within this state or who
30 proposes to engage in the manufacture, distribution, or
31 dispensing of any controlled substance within this state
32 shall obtain annually and maintain a biennial registration
33 issued by the board in accordance with its rules.

34 Sec. 6. Section 204.304, subsection 1, Code 1991, is
35 amended to add the following new paragraph:

1 NEW PARAGRAPH. d. Has committed such acts as would render
2 the registrant's registration under section 204.303
3 inconsistent with the public interest as determined under that
4 section.

5 EXPLANATION

6 Section 1 of the bill requires a nonresident pharmacy,
7 which is a pharmacy located outside of this state, which
8 delivers, dispenses, or distributes by any method,
9 prescription drugs or devices to an ultimate user in this
10 state to obtain a nonresident pharmacy license from the Iowa
11 board of pharmacy examiners. Section 1 requires payment of an
12 application fee to be determined by the board, submission of
13 an application, and of certain information including evidence
14 of a valid pharmacy license from the state in which the
15 nonresident is located. License renewal is required annually,
16 a fee for renewal is charged, and an additional fee for late
17 renewal is provided. The board is authorized to deny,
18 suspend, or revoke a nonresident license for violation of
19 certain Code provisions or rule of the board.

20 Section 2 of the bill corrects a reference to the proper
21 state agency in reference to certain pharmaceutical storage
22 regulations.

23 Section 3 of the bill allows the board to establish
24 licensure standards for prescription drug wholesalers in
25 accordance with federal law.

26 Section 4 of the bill requires licensed pharmacists to
27 report a change of name to the board.

28 Section 5 allows the board to issue biennial controlled
29 substances registrations in uniformity with section 147.100
30 which requires that licenses expire in multiyear intervals as
31 determined by the examining board.

32 Section 6 of the bill gives the board the ability to
33 suspend or revoke a controlled substances registration when
34 the registrant commits acts which are inconsistent with the
35 public health and safety. Such acts include the following:

1 failure to maintain effective controls against the diversion
2 of controlled substances; failure to comply with federal,
3 state, or local laws relating to controlled substances; and
4 any convictions under any federal or state laws relating to
5 controlled substances.

6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31

SENATE FILE 539

H-4008

1 Amend Senate File 539, as passed by the Senate, as
2 follows:
3 1. By striking page 1, line 34 through page 2,
4 line 2, and inserting the following: "distributed to
5 ultimate users in this state."

By COMMITTEE ON WAYS AND MEANS
GRONINGA of Cerro Gordo,
Chairperson

H-4008 FILED MAY 1, 1991

Adopted 5/6/91 (p. 2123)

SENATE FILE 539

H-4021

1 Amend Senate File 539, as passed by the Senate, as
2 follows:
3 1. Page 1, line 31, by inserting after the word
4 "list." the following: "All pharmacists employed by
5 the nonresident pharmacy who deliver, dispense, or
6 distribute by any method prescription drugs to an
7 ultimate user in this state shall submit evidence to
8 the board of completion of continuing education
9 requirements substantially equivalent to those
10 required pursuant to chapter 258A for pharmacists
11 licensed in this state."

By TYRRELL of Iowa

H-4021 FILED MAY 2, 1991

w/10 5/6

SENATE FILE 539

H-4065

1 Amend Senate File 539, as passed by the Senate, as
2 follows:
3 1. Page 2, line 23, by striking the word
4 "chapter," and inserting the following: "section,
5 section 155A.15, subsection 2, paragraph "a", "b",
6 "d", "e", "f", "g", "h", or "i",".

By HOLVECK of Polk

H-4065 FILED MAY 6, 1991

ADOPTED *(p. 2124)*

HOUSE AMENDMENT TO
SENATE FILE 539

S-3726

1 Amend Senate File 539, as passed by the Senate, as
2 follows:
3 1. By striking page 1, line 34 through page 2,
4 line 2, and inserting the following: "distributed to
5 ultimate users in this state."
6 2. Page 2, line 23, by striking the word
7 "chapter," and inserting the following: "section,
8 section 155A.15, subsection 2, paragraph "a", "b",
9 "d", "e", "f", "g", "h", or "i",".
10 3. By renumbering, relettering, or redesignating
11 and correcting internal references as necessary.

RECEIVED FROM THE HOUSE

S-3726 FILED MAY 7, 1991
CONCURRED (G. 1702)

**SENATE FILE 539
FISCAL NOTE**

A fiscal note for Senate File 539 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.

Senate File 539 requires an out-of-state pharmacy, which consistently dispenses prescription drugs or controlled substances to users in Iowa, obtain a pharmacy license from the Board of Pharmacy Examiners in the Department of Public Health and that the cost associated with this licensure be paid by the out-of-state pharmacy. The bill also requires the Board to develop rules concerning wholesale drug licenses, including fees and to issue biennial Controlled Substances Registrations, as compared to the current annual registration.

ASSUMPTIONS:

1. There are approximately 100 out-of-state pharmacies. The annual fee for licensure would be \$100.
 2. There are approximately 100 in-state wholesale drug licensees. The annual fee would increase from \$100 to \$300.
 3. There are approximately 9,400 Controlled Substances Registrations issued annually, which would require reorganization to be issued biennially.
- The DPH estimates an additional 1.5 FTE positions would be required to administer Senate File 413.

FISCAL EFFECT:

	<u>FY 1992</u>	<u>FY 1993</u>
<u>REVENUE</u>		
General Fund	\$ 255,208	\$ -9,000
<u>EXPENDITURES</u>		
Salaries	\$ 51,821	\$ 51,958
Support	\$ 16,845	\$ 13,115
Total	\$ 68,666	\$ 65,073
<u>NET EFFECT</u>	<u>\$ 186,542</u>	<u>\$ -74,073</u>

Note: The only new revenue to the General Fund is \$30,000 for the out-of-state pharmacy and wholesale drug licenses. The table reflects the overall result of changing from an annual to biennial registration program.

Source: Department of Public Health

(LSB 2777sv, RRS)

FILED MAY 1, 1991

BY DENNIS PROUTY, FISCAL DIRECTOR

SZYMONIAK, W.

MURPHY

HEDGE

SSB 355

WAYS + MEANS

SENATE FILE 539

BY (PROPOSED COMMITTEE ON WAYS
AND MEANS BILL BY CHAIRPERSON
DIELEMAN)

Passed Senate, Date _____ Passed House, Date _____

Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____

Approved _____

A BILL FOR

1 An Act relating to the Iowa pharmacy practice Act and assessing a
2 fee.

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

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

1 Section 1. NEW SECTION. 155A.13A OUT-OF-STATE PHARMACY
2 LICENSE.

3 1. A person who establishes, conducts, or maintains a
4 pharmacy outside of this state and who consistently,
5 regularly, or frequently ships, mails, dispenses, or delivers,
6 prescription drugs or controlled substances to ultimate users
7 in this state shall obtain a pharmacy license from the board.

8 2. The board shall adopt rules for the issuance of a
9 pharmacy license to an out-of-state pharmacy which provides
10 pharmacy services to ultimate users in this state on a
11 consistent, regular, or frequent basis. The rules shall do
12 all of the following:

13 a. Provide for designation of an agent of record,
14 conditions of licensure, compliance standards, requirements
15 pertaining to policies and procedures, disciplinary action,
16 and other relevant matters.

17 b. Exempt from licensure those out-of-state pharmacies
18 which provide pharmacy services to ultimate users in this
19 state on only an occasional, irregular, or infrequent basis.

20 c. Define, describe, and specify what constitutes the
21 provision of occasional, irregular, or infrequent pharmacy
22 services.

23 d. Require a fee for issuance of a license for an out-of-
24 state pharmacy of one hundred dollars.

25 3. If the board deems it necessary in order to carry out
26 duties imposed upon it in connection with the licensing of
27 out-of-state pharmacies under subsection 1, the board may
28 utilize its own staff or may contract with persons who are not
29 state employees for services which are necessary to conduct an
30 adequate inspection of an out-of-state pharmacy licensed by
31 the board and to adequately investigate any complaint
32 concerning or involving an out-of-state pharmacy licensed by
33 the board. The board shall assess a fee for these services,
34 whether incurred by the board's own staff or by other persons
35 under contract with the board, which shall be paid by the out-

1 of-state pharmacy who is the subject of review.

2 Sec. 2. Section 155A.15, subsection 2, paragraph d,
3 subparagraph (4), Code 1991, is amended to read as follows:

4 (4) A manufacturer or wholesaler licensed by the board.
5 However, this chapter does not prohibit a pharmacy from
6 furnishing a prescription drug or device to a licensed health
7 care facility for storage in a secured emergency
8 pharmaceutical supplies container maintained within the
9 facility in accordance with regulations rules of the Iowa
10 department of public-health inspections and appeals.

11 Sec. 3. Section 155A.17, Code 1991, is amended to read as
12 follows:

13 155A.17 WHOLESALE DRUG LICENSE.

14 1. A person shall not establish, conduct, or maintain a
15 wholesale drug business as defined in this chapter without a
16 license. The license shall be identified as a wholesale drug
17 license.

18 2. The board shall establish standards for drug wholesaler
19 licensure and may deny, suspend, or revoke a drug wholesale
20 license for failure to meet the standards or for a violation
21 of the laws of this state, another state, or the United States
22 relating to prescription drugs or controlled substances, or
23 for a violation of this chapter, chapter 203B, 204, 204A,
24 204B, or 205, or a rule of the board.

25 3. The board shall adopt rules pursuant to chapter 17A on
26 matters pertaining to the issuance of a wholesale drug
27 license. The rules shall provide for conditions of licensure,
28 compliance standards, licensure fees, disciplinary action, and
29 other relevant matters.

30 4. This section does not apply to a manufacturer's
31 representative acting in the usual course of business or
32 employment as a manufacturer's representative.

33 Sec. 4. Section 155A.19, subsection 2, Code 1991, is
34 amended to read as follows:

35 2. A pharmacist shall report in writing to the board

1 within ten days a change of name, address, or place of
2 employment.

3 Sec. 5. Section 204.302, subsection 1, Code 1991, is
4 amended to read as follows:

5 1. Every person who manufactures, distributes, or
6 dispenses any controlled substance within this state or who
7 proposes to engage in the manufacture, distribution, or
8 dispensing of any controlled substance within this state,
9 shall obtain ~~annually~~ and maintain a biennial registration
10 issued by the board in accordance with its rules.

11 Sec. 6. Section 204.304, subsection 1, Code 1991, is
12 amended by adding the following new paragraph:

13 NEW PARAGRAPH. d. Has committed such acts as would render
14 the registrant's registration under section 204.303
15 inconsistent with the public interest as determined under that
16 section.

17 EXPLANATION

18 Section 1 requires that an out-of-state pharmacy which
19 consistently, regularly, or frequently ships, mails,
20 dispenses, or delivers prescription drugs or controlled
21 substances to ultimate users in Iowa must obtain a pharmacy
22 license from the Iowa board of pharmacy examiners. A license
23 fee of \$100 is required. The board is required to adopt rules
24 to issue licenses. Section 1 also authorizes the board to use
25 its own staff or contract with persons who are not state
26 employees to conduct an adequate inspection of an out-of-state
27 pharmacy licensed by the board or to adequately investigate
28 such a pharmacy. This section provides that the costs of
29 these services shall be paid by the out-of-state pharmacy
30 which is the subject of the review.

31 Section 2 of the bill corrects a reference to the proper
32 state agency in reference to certain pharmaceutical storage
33 regulations.

34 Section 3 of the bill allows the board to establish
35 licensure standards for prescription drug wholesalers in

1 accordance with federal law.

2 Section 4 of the bill requires licensed pharmacists to
3 report a change of name to the board.

4 Section 5 allows the board to issue biennial controlled
5 substances registrations in uniformity with section 147.100
6 which requires that licenses expire in multiyear intervals as
7 determined by the examining board.

8 Section 6 of the bill gives the board the ability to
9 suspend or revoke a controlled substances registration when
10 the registrant commits acts which are inconsistent with the
11 public health and safety. Such acts include the following:
12 failure to maintain effective controls against the diversion
13 of controlled substances; failure to comply with federal,
14 state, or local laws relating to controlled substances; and
15 any convictions under any federal or state laws relating to
16 controlled substances.

17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35

SENATE FILE 539

AN ACT

RELATING TO THE IOWA PHARMACY PRACTICE ACT AND ASSESSING FEES.

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

Section 1. NEW SECTION. 155A.13A NONRESIDENT PHARMACY LICENSE -- REQUIRED, RENEWAL, DISCIPLINE.

1. LICENSE REQUIRED. A pharmacy located outside of this state which delivers, dispenses, or distributes by any method, prescription drugs or devices to an ultimate user in this state shall obtain a nonresident pharmacy license from the board. The board shall make available an application form for a nonresident pharmacy license and shall require such information it deems necessary to fulfill the purposes of this section. A nonresident pharmacy shall do all of the following in order to obtain a nonresident pharmacy license from the board:

a. Submit a completed application form and an application fee as determined by the board.

b. Submit evidence of possession of a valid license, permit, or registration as a pharmacy in compliance with the laws of the state in which it is located, a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located, and evidence of compliance with all legal directions and requests for information issued by the regulatory or licensing agency of the state in which it is located.

c. Submit a list of the name, titles, and location of all principal owners, partners, or officers of the nonresident pharmacy, all pharmacists employed by the nonresident pharmacy who deliver, dispense, or distribute by any method prescription drugs to an ultimate user in this state, and of

the pharmacist in charge of the nonresident pharmacy. A nonresident pharmacy shall update the list within thirty days of any addition, deletion, or other change to the list.

d. Submit evidence that the nonresident pharmacy maintains records of the controlled substances delivered, dispensed, or distributed to ultimate users in this state.

e. Submit evidence that the nonresident pharmacy provides, during its regular hours of operation for at least six days and for at least forty hours per week, toll-free telephone service to facilitate communication between ultimate users in this state and a pharmacist who has access to the ultimate user's records in the nonresident pharmacy, and that the toll-free number is printed on the label affixed to each container of prescription drugs delivered, dispensed, or distributed in this state.

2. LICENSE RENEWAL. A nonresident pharmacy shall renew its license on or before January 1 annually. In order to renew a nonresident pharmacy license, a nonresident pharmacy shall submit a renewal fee as determined by the board, and shall fulfill all of the requirements of subsection 1, paragraphs "b" through "e". A nonresident pharmacy shall pay an additional fee for late renewal for failure to renew a license within thirty-one days after expiration of the license.

3. DISCIPLINE. The board may deny, suspend, or revoke a nonresident pharmacy license for any violation of this section, section 155A.15, subsection 2, paragraph "a", "b", "d", "e", "f", "g", "h", or "i", chapter 203B, 204, 204A, 204B, or 205, or a rule of the board.

Sec. 2. Section 155A.15, subsection 2, paragraph d, subparagraph (4), Code 1991, is amended to read as follows:

(4) A manufacturer or wholesaler licensed by the board. However, this chapter does not prohibit a pharmacy from furnishing a prescription drug or device to a licensed health care facility for storage in a secured emergency

pharmaceutical supplies container maintained within the facility in accordance with regulations rules of the Iowa department of public-health inspections and appeals.

Sec. 3. Section 155A.17, Code 1991, is amended to read as follows:

155A.17 WHOLESALE DRUG LICENSE.

1. A person shall not establish, conduct, or maintain a wholesale drug business as defined in this chapter without a license. The license shall be identified as a wholesale drug license.

2. The board shall establish standards for drug wholesaler licensure and may deny, suspend, or revoke a drug wholesale license for failure to meet the standards or for a violation of the laws of this state, another state, or the United States relating to prescription drugs or controlled substances, or for a violation of this chapter, chapter 203B, 204, 204A, 204B, or 205, or a rule of the board.

3. The board shall adopt rules pursuant to chapter 17A on matters pertaining to the issuance of a wholesale drug license. The rules shall provide for conditions of licensure, compliance standards, licensure fees, disciplinary action, and other relevant matters.

4. This section does not apply to a manufacturer's representative acting in the usual course of business or employment as a manufacturer's representative.

Sec. 4. Section 155A.19, subsection 2, Code 1991, is amended to read as follows:

2. A pharmacist shall report in writing to the board within ten days a change of name, address, or place of employment.

Sec. 5. Section 204.302, subsection 1, Code 1991, is amended to read as follows:

1. Every person who manufactures, distributes, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, distribution, or

dispensing of any controlled substance within this state, shall obtain annually and maintain a biennial registration issued by the board in accordance with its rules.

Sec. 6. Section 204.304, subsection 1, Code 1991, is amended by adding the following new paragraph:

NEW PARAGRAPH. d. Has committed such acts as would render the registrant's registration under section 204.303 inconsistent with the public interest as determined under that section.

.....
JOE J. WELSH
President of the Senate

.....
ROBERT C. ARNOULD
Speaker of the House

I hereby certify that this bill originated in the Senate and is known as Senate File 539, Seventy-fourth General Assembly.

.....
JOHN F. DWYER
Secretary of the Senate

Approved June 4, 1991

.....
TERRY E. BRANSTAD
Governor