

Senate Study Bill 1108

SENATE/HOUSE FILE _____
BY (PROPOSED DEPARTMENT OF
PUBLIC HEALTH/BOARD OF
PHARMACY EXAMINERS BILL)

Passed Senate, Date _____ Passed House, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act providing for changes relating to pharmaceutical practice
2 and the regulation of licensed pharmacists, and making
3 penalties applicable.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
5 TLSB 1185DP 80
6 rn/cl/14

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1 1 Section 1. NEW SECTION. 155A.40 CONTINUOUS QUALITY
1 2 IMPROVEMENT PROGRAM.
1 3 1. Each licensed pharmacy shall implement a continuous
1 4 quality improvement program to review pharmacy procedures in
1 5 order to identify methods for addressing pharmacy medication
1 6 errors and for improving patient use of medications and
1 7 patient care services. Under the program, each pharmacy shall
1 8 assess its practices and identify areas for quality
1 9 improvement.
1 10 2. The board shall adopt rules for the administration of a
1 11 continuous quality improvement program. The rules shall
1 12 address all of the following:
1 13 a. Program requirements and procedures.
1 14 b. Program record and reporting requirements.
1 15 c. Any other provisions necessary for the administration
1 16 of a program.
1 17 3. Any record or report generated solely for and
1 18 maintained by a pharmacy as a component of the pharmacy's
1 19 continuous quality improvement program shall not be subject to
1 20 discovery in any civil proceeding. However, this subsection
1 21 shall not prohibit the board or other authorized government
1 22 agency from reviewing or having access to the record or report
1 23 as necessary to protect the public health and safety.
1 24 Sec. 2. NEW SECTION. 155A.41 INTERNET DRUG DELIVERY ==
1 25 CITATIONS.
1 26 1. A licensee or other person or entity shall not
1 27 dispense, furnish, or cause to be dispensed or furnished a
1 28 prescription drug as defined in section 155A.3, via the
1 29 internet for delivery in this state without a valid
1 30 prescription drug order as defined in section 155A.3, nor with
1 31 a prescription drug order if the licensee, person, or entity
1 32 either knew or reasonably should have known that the
1 33 prescription drug order was not issued pursuant to a valid
1 34 physician-patient relationship, or if the licensee, person, or
1 35 entity did not act in accordance with the requirements of
2 1 section 205.3 and rules established by the board.
2 2 2. The board shall establish by rule procedures relating
2 3 to the investigation of complaints regarding internet drug
2 4 deliveries that do not comply with the provisions of
2 5 subsection 1, and the issuance of citations and imposition of
2 6 penalties for noncompliance. Citations issued by the board
2 7 for noncompliance with subsection 1 shall be in writing, and
2 8 shall specify the violation or violations that have been the
2 9 subject of the allegation of noncompliance, the findings of
2 10 the board, an order of abatement fixing a reasonable time for
2 11 such abatement prior to the issuance of an injunction pursuant
2 12 to section 155A.5, when appropriate, and the imposition of any
2 13 fines, civil penalties, or other disciplinary actions. The
2 14 contested case procedures of chapter 17, the provisions of
2 15 sections 155A.18 and 272C.3, and rules adopted by the board
2 16 shall apply regarding board authority, investigative
2 17 procedures and hearings, and the imposition of fines and
2 18 penalties. Notwithstanding any other provision of law to the
2 19 contrary, a violation of this section may subject the
2 20 licensee, person, or entity to a fine or civil penalty of up
2 21 to twenty-five thousand dollars per occurrence. In assessing

2 22 a fine for a violation of subsection 1, the board shall give
2 23 due consideration to the gravity of the violation, good faith
2 24 of the licensee, person, or entity, and history of previous
2 25 internet drug delivery violations by the licensee, person, or
2 26 entity in this or any other state.

2 27 3. In the event that a citation has been issued to a
2 28 licensee and a fine imposed pursuant to this section, and the
2 29 licensee has not contested the citation nor paid in full the
2 30 fine within thirty days of receipt of the citation, the full
2 31 amount of the assessed fine shall be added to the fee for
2 32 license renewal and the person's license shall not be renewed
2 33 by the board until full payment is received. Any amount due
2 34 under this section may be set off against any claims due the
2 35 licensee, person, or entity as provided in section 421.17,
3 1 subsection 29, and any amount transferred to the board under
3 2 that provision shall be deposited in the fund established
3 3 pursuant to subsection 4.

3 4 4. Fines and civil penalties collected pursuant to this
3 5 section shall be deposited in a special fund established
3 6 within the state treasury under the authority of the board.
3 7 Moneys deposited in the special fund shall be considered
3 8 repayment receipts as defined in section 8.2 and shall be
3 9 utilized by the board for administration and enforcement of
3 10 this section. Funds may be used by the board to investigate
3 11 allegations of noncompliance with this section, to enforce
3 12 orders, and for payment of personal services and related
3 13 expenses of an investigator, attorney general fees and costs,
3 14 and administrative costs incurred by the board.
3 15 Notwithstanding section 8.33, moneys deposited in the special
3 16 fund that remain unencumbered or unobligated at the close of
3 17 the fiscal year shall not revert to any other fund but shall
3 18 remain available for expenditure for the purposes designated
3 19 in future fiscal years. Notwithstanding section 12C.7,
3 20 subsection 2, interest or earnings on moneys deposited into
3 21 the special fund shall be credited to and remain a part of the
3 22 special fund.

3 23 Sec. 3. NEW SECTION. 155A.42 PHARMACY ADVANCEMENT FUND.

3 24 A pharmacy advancement fund is created in the state
3 25 treasury under the control of the board to assist the board in
3 26 promoting, preserving, and protecting the public health,
3 27 safety, and welfare through the effective regulation of the
3 28 practice of pharmacy and the distribution of prescription
3 29 drugs and devices in the state. Amounts appropriated to,
3 30 received by, and deposited in the fund are appropriated to the
3 31 board to assist with the regulation of pharmacy operations,
3 32 the appropriate utilization of pharmacy technicians and other
3 33 pharmacy assistants, and pharmacist education and training.
3 34 Notwithstanding any other provision to the contrary, the board
3 35 may accept, transfer, or expend funds appropriated or made
4 1 available by any public or private source to be used in
4 2 furtherance of the objectives stated in this section.
4 3 Notwithstanding section 8.33, moneys deposited in the fund
4 4 that remain unencumbered or unobligated at the close of the
4 5 fiscal year shall not revert but shall remain available for
4 6 expenditure for the purposes designated in future fiscal
4 7 years. The board shall adopt rules necessary for the
4 8 implementation of this section.

4 9 Sec. 4. Section 272C.6, subsection 6, unnumbered paragraph
4 10 1, Code 2003, is amended to read as follows:

4 11 A board created pursuant to chapter 147, 154A, 155, 169,
4 12 542, 542B, 543B, 543D, 544A, or 544B may charge a fee not to
4 13 exceed ~~seventy-five~~ two hundred fifty dollars for conducting a
4 14 disciplinary hearing pursuant to this chapter which results in
4 15 disciplinary action taken against the licensee by the board,
4 16 and in addition to the fee, may recover from a licensee the
4 17 costs for the following procedures and associated personnel:

4 18 EXPLANATION

4 19 This bill provides for several changes relating to
4 20 pharmaceutical practice and the regulation of licensed
4 21 pharmacists and pharmacies.

4 22 The bill provides that each licensed pharmacy shall
4 23 implement a continuous quality improvement program to review
4 24 pharmacy procedures in order to identify methods for
4 25 addressing pharmacy medication errors and for improving
4 26 patient use of medications and patient care services. The
4 27 bill provides that the board of pharmacy examiners shall adopt
4 28 rules for the administration of the program.

4 29 The bill also establishes a new Code section relating to
4 30 internet prescription drug deliveries. The bill provides that
4 31 a licensee, person, or entity shall not dispense, furnish, or
4 32 cause to be dispensed or furnished a prescription drug via the

4 33 internet for delivery within the state without a prescription
4 34 drug order, nor with a prescription drug order if the
4 35 licensee, person, or entity either knew or reasonably should
5 1 have known that the prescription drug order was not issued
5 2 pursuant to a valid physician-patient relationship, or if the
5 3 licensee, person, or entity did not act in accordance with the
5 4 requirements of Code section 205.3 and rules established by
5 5 the board. Code section 205.3 provides for written
5 6 prescriptions being dispensed only under specified
5 7 circumstances relating to a medical, dental, or veterinary
5 8 purpose. The bill provides that the board of pharmacy
5 9 examiners shall establish by rule procedures relating to the
5 10 investigation of complaints regarding internet drug deliveries
5 11 and the issuance of citations and imposition of penalties for
5 12 noncompliance. The bill provides that the contested case
5 13 procedures of Code chapter 17, penalty provisions of Code
5 14 sections 155A.18 and 272C.3, and rules adopted by the board
5 15 shall apply regarding board authority, investigative
5 16 procedures and hearings, and the imposition of and amount of
5 17 fines and penalties. The bill provides that a fine or penalty
5 18 of up to \$25,000 per occurrence could be imposed by the board.
5 19 The bill provides that in assessing a fine, the board shall
5 20 give due consideration to the gravity of the violation, good
5 21 faith of the licensee, person, or entity, and history of
5 22 previous internet drug delivery violations.

5 23 The bill additionally provides that if a licensee has not
5 24 contested a citation and has not paid in full a fine within 30
5 25 days of receipt of a citation, the full amount of the assessed
5 26 fine shall be added to the fee for license renewal and a
5 27 license shall not be renewed by the board until full payment
5 28 is received. The bill further provides that any amount due
5 29 may be set off against any claims for tax refunds or lottery
5 30 winnings due the licensee, person, or entity pursuant to Code
5 31 section 421.17, subsection 29, and the amount transferred to
5 32 the board and deposited in a fund established for
5 33 administration and enforcement of this new Code section. The
5 34 bill provides that the fund would contain the fines and civil
5 35 penalties collected for violation of the internet drug
6 1 delivery policy, and would be used by the board to investigate
6 2 allegations of noncompliance, to enforce orders, and for
6 3 payment of personal services and related expenses of an
6 4 investigator, attorney general fees and costs, and
6 5 administrative costs. The bill provides that the amounts
6 6 deposited would be considered repayment receipts pursuant to
6 7 Code section 8.2.

6 8 The bill provides for the creation of a pharmacy
6 9 advancement fund in the state treasury under the control of
6 10 the board of pharmacy examiners. The bill provides that the
6 11 fund would assist the board in promoting, preserving, and
6 12 protecting the public health, safety, and welfare through the
6 13 effective regulation of the practice of pharmacy and the
6 14 distribution of prescription drugs and devices in the state.
6 15 The bill provides that amounts appropriated to, received by,
6 16 and deposited in the fund are appropriated to the board to
6 17 assist with the regulation of pharmacy operations, the
6 18 appropriate utilization of pharmacy technicians and other
6 19 pharmacy assistants, and pharmacist education and training.
6 20 The bill provides that notwithstanding any other provision to
6 21 the contrary, the board may accept, transfer, and expend funds
6 22 appropriated or made available by any public or private source
6 23 to be used in furtherance of these objectives. The bill
6 24 provides for the adoption by the board of rules relating to
6 25 implementation of provisions relating to the fund.

6 26 The bill also provides for an increase in the amount of the
6 27 fee authorized in Code section 272C.6 to be charged by
6 28 specified boards for conducting a disciplinary hearing from
6 29 \$75 to \$250.
6 30 LSB 1185DP 80
6 31 rn/cl/14.1