House Study Bill 241

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 _	
	A	oproved		-		

A BILL FOR

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

6 rn/cl/14

PAG LIN

1

1

1 13

1 14

1 15

1 17

1

2 2

2 2

Section 1. <u>NEW SECTION</u>. 155A.40 CONTINUOUS QUALITY 1 1

2 IMPROVEMENT PROGRAM.
3 1. Each licensed pharmacy shall implement a continuous 4 quality improvement program to review pharmacy procedures in 5 order to identify methods for addressing pharmacy medication 6 errors and for improving patient use of medications and 7 patient care services. Under the program, each pharmacy shall 8 assess its practices and identify areas for quality 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:
 - a. Program requirements and procedures.
 - b. Program record and reporting requirements.
- c. Any other provisions necessary for the administration 1 16 of a program.
- 3. Any record or report generated solely for and 1 18 maintained by a pharmacy as a component of the pharmacy's 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 22 agency from reviewing or having access to the record or report 23 as necessary to protect the public health and safety Sec. 2.
- 1 24 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 29 internet for delivery in this state without a valid 30 prescription drug order as defined in section 155A.3, nor with 1 31 a prescription drug order if the licensee, person, or entity 32 either knew or reasonably should have known that the 33 prescription drug order was not issued pursuant to a valid 1 34 physician=patient relationship, or if the licensee, person, or 35 entity did not act in accordance with the requirements of
 - 3 to the investigation of complaints regarding internet drug 4 deliveries that do not comply with the provisions of 5 subsection 1, and the issuance of citations and imposition of

6 penalties for noncompliance. Citations issued by the board 7 for noncompliance with subsection 1 shall be in writing, and 8 shall specify the violation or violations that have been the 9 subject of the allegation of noncompliance, the findings of 2 10 the board, an order of abatement fixing a reasonable time for 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
- 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.

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

3

3

3 23

4

4

4

4

4 18

4 19

4 22

4

4. Fines and civil penalties collected pursuant to this 5 section shall be deposited in a special fund established 6 within the state treasury under the authority of the board. 7 Moneys deposited in the special fund shall be considered 8 repayment receipts as defined in section 8.2 and shall be 9 utilized by the board for administration and enforcement of 10 this section. Funds may be used by the board to investigate 11 allegations of noncompliance with this section, to enforce 3 12 orders, and for payment of personal services and related 13 expenses of an investigator, attorney general fees and costs, 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.

Sec. 3. NEW SECTION. 155A.42 PHARMACY ADVANCEMENT FUND. A pharmacy advancement fund is created in the state 3 25 treasury under the control of the board to assist the board in 26 promoting, preserving, and protecting the public health, 27 safety, and welfare through the effective regulation of the 28 practice of pharmacy and the distribution of prescription 3 29 drugs and devices in the state. Amounts appropriated to, 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 33 pharmacy assistants, and pharmacist education and training. 34 Notwithstanding any other provision to the contrary, the board 35 may accept, transfer, or expend funds appropriated or made 1 available by any public or private source to be used in 2 furtherance of the objectives stated in this section. 3 Notwithstanding section 8.33, moneys deposited in the fund 4 that remain unencumbered or unobligated at the close of the 5 fiscal year shall not revert but shall remain available for 6 expenditure for the purposes designated in future fiscal years. The board shall adopt rules necessary for the 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: 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: EXPLANATION

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

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

The bill also establishes a new Code section relating to 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 1 have known that the prescription drug order was not issued 2 pursuant to a valid physician=patient relationship, or if the 3 licensee, person, or entity did not act in accordance with the 4 requirements of Code section 205.3 and rules established by 5 the board. Code section 205.3 provides for written 6 prescriptions being dispensed only under specified 7 circumstances relating to a medical, dental, or veterinary 8 purpose. The bill provides that the board of pharmacy 9 examiners shall establish by rule procedures relating to the 5 10 investigation of complaints regarding internet drug deliveries 11 and the issuance of citations and imposition of penalties for 12 noncompliance. The bill provides that the contested case 5 12 noncompliance. 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 17 fines and penalties. The bill provides that a fine or penalty 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 21 faith of the licensee, person, or entity, and history of 22 previous internet drug delivery violations. The bill additionally provides that if a licensee has not 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

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

The bill provides for the creation of a pharmacy 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. 20 The bill provides that notwithstanding any other provision to 21 the contrary, the board may accept, transfer, and expend funds 6 22 appropriated or made available by any public or private source 23 to be used in furtherance of these objectives. The bill 24 provides for the adoption by the board of rules relating to 6 25 implementation of provisions relating to the fund.

The bill also provides for an increase in the amount of the 26 27 fee authorized in Code section 272C.6 to be charged by 28 specified boards for conducting a disciplinary hearing from 29 \$75 to \$250.

30 LSB 1185DP 80

6 31 rn/cl/14.1

5

6

6 6

6 6

6

6

6

6

6

6