Senate Study Bill 1183 - Introduced

SENATE FILE _____
BY (PROPOSED COMMITTEE ON HUMAN RESOURCES BILL BY CHAIRPERSON RAGAN)

A BILL FOR

An Act relating to drug product selection.

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

S.F. _____

Section 1. Section 155A.13A, Code 2013, is amended to read as follows:

155A.13A Nonresident pharmacy license — required, renewal, <u>drug product selection,</u> 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 names, titles, and locations 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 as determined by the board.

3. *Drug product selection.* A nonresident pharmacy is subject to the drug product selection requirements specified in section 155A.32.

~~3.~~ 4. *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 124, 124A, 124B, 126, or 205, or a rule of the board.

Sec. 2. Section 155A.32, subsection 2, Code 2013, is amended to read as follows:

2. The pharmacist shall not exercise the drug product selection described in this section if ~~either~~ any of the following is true:

a. The prescriber specifically indicates that no drug product selection shall be made.

b. The person presenting the prescription indicates that only the specific drug product prescribed should be dispensed. However, this paragraph does not apply if the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A.

c. The prescriber indicates that a specific drug product should be dispensed and a diagnosis of epilepsy is written on the prescription. For the purposes of this paragraph, "*drug product selection*" includes dispensing a drug product of another manufacturer instead of the specific drug product the patient is currently prescribed, and substituting a generic version for a brand version, a brand version for a generic version, or a generic version for a generic version of a different manufacturer. For the purposes of this paragraph, a "*specific drug product*" means a specific drug, strength, dosage form, or dosing regimen from a specific manufacturer.

Sec. 3. Section 155A.32, Code 2013, is amended by adding the following new subsections:

NEW SUBSECTION. 4. If drug product selection is prohibited pursuant to subsection 2, paragraph "*c*", but the specific drug indicated is not available, the pharmacist may dispense a seventy-two-hour emergency supply of a bioequivalent of a specific generic manufacturer's product. If a pharmacist dispenses a bioequivalent drug product under this subsection, the pharmacist shall notify the patient and the prescriber of the substitution and shall resolve the shortage within seventy-two hours of dispensing the substitute drug product. The board shall adopt rules regarding notification of the patient and prescriber under this subsection.

NEW SUBSECTION. 5. If drug product selection is prohibited under subsection 2, paragraph "*c*", any differential in cost to the pharmacy or patient resulting from the prohibition shall be covered by the patient's health carrier as defined in section 514J.102.

EXPLANATION

This bill relates to drug product selection.

The bill amends provisions relating to nonresident pharmacies to provide that a nonresident pharmacy is subject to the drug product selection requirements that are currently applicable to resident pharmacies.

The bill also amends the list of exceptions to a pharmacist exercising drug product selection to provide that a pharmacist shall not exercise drug product selection if the prescriber indicates that a specific drug product should be dispensed and a diagnosis of epilepsy is written on the prescription. The bill also specifies that for the purposes of the exception, drug product selection includes dispensing a drug product of another manufacturer instead of the specific drug product the patient is currently prescribed, and substituting a generic version for a brand version, a brand version for a generic version, or a generic version for a generic version of a different manufacturer. Additionally, for the purposes of the exception, a specific drug product means a specific drug, strength, dosage form, or dosing regimen from a specific manufacturer.

The bill also addresses substitutions made when a pharmacy does not have a specific drug product available when drug product selection is prohibited. In those instances, the bill provides that the pharmacist may dispense a 72-hour emergency supply of a bioequivalent of a specific generic manufacturer's product. If a substitute is dispensed, the pharmacist is required to notify the patient and the prescriber of the substitution and to resolve the shortage within 72 hours of dispensing the substitute drug product. The bill directs the board of pharmacy to adopt rules regarding notification of the patient and prescriber.

The bill also provides that if drug product selection is prohibited relating to a diagnosis of epilepsy, any differential in cost to the pharmacy or patient resulting from the prohibition shall be covered by the patient's health carrier.