

House File 798 - Introduced

HOUSE FILE _____
BY COMMITTEE ON STATE
GOVERNMENT

(SUCCESSOR TO HSB 109)

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

A BILL FOR

1 An Act relating to the regulation of pharmacy benefits managers
2 and providing penalties.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
4 TLSB 1827HV 82
5 pf/gg/14

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1 1 Section 1. NEW SECTION. 155B.1 DEFINITIONS.
1 2 As used in this chapter, unless the context otherwise
1 3 requires:
1 4 1. "Commissioner" means the commissioner of insurance.
1 5 2. "Covered entity" means a nonprofit hospital or medical
1 6 services corporation, health insurer, health benefit plan, or
1 7 health maintenance organization; a health program administered
1 8 by a department or the state in the capacity of provider of
1 9 health coverage; or an employer, labor union, or other group
1 10 of persons organized in the state that provides health
1 11 coverage. "Covered entity" does not include a self-funded
1 12 health coverage plan that is exempt from state regulation
1 13 pursuant to the federal Employee Retirement Income Security
1 14 Act of 1974 (ERISA), as codified at 29 U.S.C. } 1001 et seq.,
1 15 a plan issued for health coverage for federal employees, or a
1 16 health plan that provides coverage only for accidental injury,
1 17 specified disease, hospital indemnity, Medicare supplemental,
1 18 disability income, or long-term care, or other limited benefit
1 19 health insurance policy or contract.
1 20 3. "Covered individual" means a member, participant,
1 21 enrollee, contract holder, policyholder, or beneficiary of a
1 22 covered entity who is provided health coverage by the covered
1 23 entity, and includes a dependent or other person provided
1 24 health coverage through a policy, contract, or plan for a
1 25 covered individual.
1 26 4. "Generic drug" means a chemically equivalent copy of a
1 27 brand-name drug with an expired patent.
1 28 5. "Labeler" means a person that receives prescription
1 29 drugs from a manufacturer or wholesaler and repackages those
1 30 drugs for later retail sale and that has a labeler code from
1 31 the federal food and drug administration pursuant to 21 C.F.R.
1 32 } 207.20.
1 33 6. "Pharmacy" means pharmacy as defined in section 155A.3.
1 34 7. "Pharmacy benefits management" means the procurement of
1 35 prescription drugs at a negotiated rate for dispensing within
2 1 this state to covered individuals, the administration or
2 2 management of prescription drug benefits provided by a covered
2 3 entity for the benefit of covered individuals, or any of the
2 4 following services provided with regard to the administration
2 5 of the following pharmacy benefits:
2 6 a. Mail service pharmacy.
2 7 b. Claims processing, retail network management, or
2 8 payment of claims to pharmacies for prescription drugs
2 9 dispensed to covered individuals.
2 10 c. Clinical formulary development and management services.
2 11 d. Rebate contracting and administration.
2 12 e. Certain patient compliance, therapeutic intervention,
2 13 or generic substitution programs.
2 14 f. Disease management programs involving prescription drug
2 15 utilization.
2 16 8. "Pharmacy benefits manager" means a person who performs
2 17 pharmacy benefits management services. "Pharmacy benefits

2 18 manager" includes a person acting on behalf of a pharmacy
2 19 benefits manager in a contractual or employment relationship
2 20 in the performance of pharmacy benefits management services
2 21 for a covered entity. "Pharmacy benefits manager" does not
2 22 include a health insurer licensed in the state if the health
2 23 insurer or its subsidiary is providing pharmacy benefits
2 24 management services to its own insurers, or a public
2 25 self-funded pool or a private single employer self-funded plan
2 26 that provides such benefits or services directly to its
2 27 beneficiaries.

2 28 9. "Prescription drug" means prescription drug as defined
2 29 in section 155A.3.

2 30 10. "Prescription drug order" means prescription drug
2 31 order as defined in section 155A.3.

2 32 11. "Proprietary information" means information on
2 33 pricing, costs, revenue, taxes, market share, negotiating
2 34 strategies, customers, or personnel held by a private entity
2 35 and used for that private entity's business purposes.

3 1 12. "Trade secret" means trade secret as defined in
3 2 section 550.2.

3 3 Sec. 2. NEW SECTION. 155B.2 PHARMACY BENEFITS MANAGER ==
3 4 LICENSE == FEE == PENALTY.

3 5 1. A person shall not perform or act as a pharmacy
3 6 benefits manager in this state without obtaining an annual
3 7 license to do business in this state from the commissioner
3 8 pursuant to this section. The commissioner shall adopt rules,
3 9 pursuant to chapter 17A, relating to the issuance of a license
3 10 under this section. The rules shall include but not be
3 11 limited to all of the following:

3 12 a. Definition of terms.

3 13 b. Use of prescribed forms.

3 14 c. Reporting requirements.

3 15 d. Enforcement procedures.

3 16 e. Protection of proprietary information and trade
3 17 secrets.

3 18 f. Pharmacy auditing practices.

3 19 g. Termination of pharmacy agreements.

3 20 h. Timely payment of pharmacy claims.

3 21 i. Methods of adjudication of complaints and settlement of
3 22 disputes between a pharmacy benefits manager and a licensed
3 23 pharmacy.

3 24 j. Information to be included in the application for
3 25 licensure including the names, addresses, official positions,
3 26 and professional qualifications of the individuals who are
3 27 responsible for control of the pharmacy benefits manager,
3 28 including all members of the board of directors, board of
3 29 trustees, executive committee, or other governing board or
3 30 committee, the principal officers in the case of a
3 31 corporation, the partners or members in the case of a
3 32 partnership or association, and any other person who exercises
3 33 control over the pharmacy benefits manager; and the name and
3 34 address of the agent for service of process in the state.

3 35 k. The filing fee.

4 1 1. Requirements for renewal of licensure.

4 2 2. A person applying for a license shall pay a filing fee
4 3 of one thousand dollars.

4 4 3. A pharmacy benefits manager shall renew the license on
4 5 an annual basis.

4 6 4. A pharmacy benefits manager who operates without
4 7 obtaining a license under this section is subject to a fine of
4 8 not less than one thousand five hundred dollars.

4 9 Sec. 3. NEW SECTION. 155B.3 PERFORMANCE OF DUTIES ==
4 10 GOOD FAITH == CONFLICT OF INTEREST.

4 11 1. A pharmacy benefits manager shall perform the pharmacy
4 12 benefits manager's duties exercising good faith and fair
4 13 dealing toward the covered entity and covered individuals.

4 14 2. A pharmacy benefits manager shall notify the covered
4 15 entity in writing of any activity, policy, practice ownership
4 16 interest, or affiliation of the pharmacy benefits manager that
4 17 directly or indirectly presents any conflict of interest.

4 18 Sec. 4. NEW SECTION. 155B.4 DISCLOSURE OF REVENUES
4 19 RECEIVED FROM PHARMACEUTICAL MANUFACTURER OR LABELER UNDER
4 20 CONTRACT == CONTENT FEES.

4 21 1. A covered entity may request that any pharmacy benefits
4 22 manager with which it has a contract for pharmacy benefits
4 23 management disclose to the covered entity each pharmaceutical
4 24 manufacturer or labeler with whom the pharmacy benefits
4 25 manager has a contract. The pharmacy benefits manager shall
4 26 disclose all of the following in writing:

4 27 a. The aggregate amount and, for a list of drugs to be
4 28 specified in the contract, the specific amount of all rebates

4 29 and other retrospective utilization discounts received by the
4 30 pharmaceutical manufacturer or labeler that is earned in
4 31 connection with the dispensing of prescription drugs to
4 32 covered individuals of the health benefit plans issued by the
4 33 covered entity or for which the covered entity is the
4 34 designated administrator.

4 35 b. The nature, type, and amount of all other revenue
5 1 received by the pharmacy benefits manager directly or
5 2 indirectly from each pharmaceutical manufacturer or labeler
5 3 for any other products or services provided to the
5 4 pharmaceutical manufacturer or labeler by the pharmacy
5 5 benefits manager with respect to programs that the covered
5 6 entity offers or provides to its enrollees.

5 7 c. Any prescription drug utilization information requested
5 8 by the covered entity relating to covered individuals.

5 9 2. A pharmacy benefits manager shall provide the
5 10 information requested by the covered entity for such
5 11 disclosure within thirty days of receipt of a request. If
5 12 requested, the information shall be provided at least once
5 13 each year. The contract entered into between the pharmacy
5 14 benefits manager and the covered entity shall specify any fees
5 15 to be charged for drug utilization reports requested by the
5 16 covered entity.

5 17 Sec. 5. NEW SECTION. 155B.5 CONTACTING COVERED
5 18 INDIVIDUAL == REQUIREMENTS.

5 19 A pharmacy benefits manager, unless authorized pursuant to
5 20 the terms of its contract with a covered entity, shall not
5 21 contact any covered individual without the express written
5 22 permission of the covered entity.

5 23 Sec. 6. NEW SECTION. 155B.6 CONFIDENTIALITY OF
5 24 INFORMATION == INJUNCTION == DAMAGES.

5 25 1. With the exception of utilization information, a
5 26 covered entity shall maintain any information disclosed in
5 27 response to a request pursuant to section 155B.4 as
5 28 confidential and proprietary information, and shall not use
5 29 such information for any other purpose or disclose such
5 30 information to any other person except as provided in this
5 31 chapter or in the contract between the pharmacy benefits
5 32 manager and the covered entity.

5 33 2. A covered entity that discloses information in
5 34 violation of this section is subject to an action for
5 35 injunctive relief and is liable for any damages which are the
6 1 direct and proximate result of such disclosure.

6 2 3. This section does not prohibit a covered entity from
6 3 disclosing confidential or proprietary information to the
6 4 commissioner, upon request. Any such information obtained by
6 5 the commissioner is confidential and privileged and is not
6 6 open to public inspection or disclosure.

6 7 Sec. 7. NEW SECTION. 155B.7 AUDIT OF RECORDS.

6 8 A covered entity may have the pharmacy benefits manager's
6 9 records related to the rebates or other information described
6 10 in section 155B.4 audited, to the extent the information
6 11 relates directly or indirectly to the covered entity's
6 12 contract, in accordance with the terms of the contract between
6 13 the pharmacy benefits manager and the covered entity.
6 14 However, if the parties have not expressly provided for audit
6 15 rights and the pharmacy benefits manager has advised the
6 16 covered entity that other reasonable options are available and
6 17 subject to negotiation, the covered entity may have such
6 18 records audited as follows:

6 19 1. An audit may be conducted no more frequently than once
6 20 in each twelve-month period upon not less than thirty business
6 21 day's written notice to the pharmacy benefits manager.

6 22 2. The covered entity may select an independent entity to
6 23 conduct the audit, and the independent entity shall sign a
6 24 confidentiality agreement with the covered entity and the
6 25 pharmacy benefits manager ensuring that all information
6 26 obtained during the audit will be treated as confidential.
6 27 The independent entity shall not disclose or otherwise reveal
6 28 any such information in any manner or form to any person
6 29 except as otherwise permitted under the confidentiality
6 30 agreement. The covered entity shall treat all information
6 31 obtained as a result of the audit as confidential, and shall
6 32 not use or disclose such information except as may be
6 33 otherwise permitted under the terms of the contract between
6 34 the covered entity and the pharmacy benefits manager or if
6 35 ordered by a court of competent jurisdiction for good cause

7 1 shown.

7 2 3. Any audit shall be conducted at the location of the
7 3 pharmacy benefits manager where such records are located,
7 4 during normal business hours, without undue interference with

7 5 the pharmacy benefits manger's business activities, and in
7 6 accordance with reasonable audit procedures.

7 7 Sec. 8. NEW SECTION. 155B.8 DISPENSING OF SUBSTITUTE
7 8 PRESCRIPTION DRUG FOR PRESCRIBED DRUG.

7 9 1. The following provisions shall apply when a pharmacy
7 10 benefits manager requests the dispensing of a substitute
7 11 prescription drug for a prescribed drug to a covered
7 12 individual:

7 13 a. The pharmacy benefits manager may request the
7 14 substitution of a lower priced generic and therapeutically
7 15 equivalent drug for a higher priced prescribed drug.

7 16 b. If the substitute drug's net cost to the covered
7 17 individual or covered entity exceeds the cost of the
7 18 prescribed drug, the substitution shall be made only for
7 19 medical reasons that benefit the covered individual.

7 20 c. If a pharmacy benefits manager makes a substitution in
7 21 which the substitute drug costs more than the prescribed drug,
7 22 the pharmacy benefits manager shall disclose to the covered
7 23 entity and covered individual the cost of both drugs and any
7 24 benefit or payment directly or indirectly accruing to the
7 25 pharmacy benefits manager as a result of the substitution.

7 26 d. The pharmacy benefits manager shall transfer in full to
7 27 the covered entity any benefit or payment received in any form
7 28 by the pharmacy benefits manager either as a result of a
7 29 prescription drug substitution or as a result of the pharmacy
7 30 benefits manager substituting a lower priced generic and
7 31 therapeutically equivalent drug for a higher priced prescribed
7 32 drug.

7 33 2. A pharmacy benefits manager shall obtain the approval
7 34 of the prescribing practitioner prior to requesting any
7 35 substitution under this section.

8 1 3. A pharmacy benefits manager shall not substitute an
8 2 equivalent prescription drug contrary to a prescription drug
8 3 order that prohibits a substitution.

8 4 Sec. 9. NEW SECTION. 155B.9 CIVIL ACTION == ENFORCEMENT
8 5 OF CHAPTER == DAMAGES.

8 6 A covered entity may bring a civil action to enforce a
8 7 provision of this chapter or to seek civil damages for a
8 8 violation of a provision of this chapter.

8 9 Sec. 10. NEW SECTION. 155B.10 APPLICATION OF CHAPTER TO
8 10 CERTAIN CONTRACTS.

8 11 The provisions of this chapter apply only to pharmacy
8 12 benefits management services contracts entered into or renewed
8 13 on or after July 1, 2007.

8 14 Sec. 11. NEW SECTION. 155B.11 DUTIES TO PHARMACY NETWORK
8 15 PROVIDERS.

8 16 1. A pharmacy benefits manager shall not mandate basic
8 17 recordkeeping that is more stringent than that required by
8 18 state or federal law or regulation.

8 19 2. If a pharmacy benefits manager receives notice from a
8 20 covered entity of termination of the covered entity's
8 21 contract, the pharmacy benefits manager shall notify, within
8 22 ten working days of the notice, all pharmacy network providers
8 23 of the effective date of the termination.

8 24 3. Within twenty-four hours of a price increase
8 25 notification by a manufacturer or supplier, a pharmacy
8 26 benefits manager shall adjust its payment to the pharmacy
8 27 network provider consistent with the price increase.

EXPLANATION

8 28 This bill provides for the regulation of pharmacy benefits
8 29 managers. The bill provides definitions, requires that a
8 30 pharmacy benefits manager in this state obtain an annual
8 31 license from the commissioner of insurance, and directs the
8 32 commissioner of insurance to adopt rules relating to
8 33 definition of terms, use of prescribed forms, reporting
8 34 requirements, enforcement procedures, and protection of
8 35 proprietary information and trade secrets.

9 1 The bill requires pharmacy benefits managers to perform
9 2 their duties exercising good faith and fair dealing toward the
9 3 covered entity and covered individuals.

9 4 The bill provides that a covered entity may request that a
9 5 pharmacy benefits manager with which it has a contract for
9 6 pharmacy benefits management disclose to the covered entity
9 7 the amount of all rebate revenues and the nature, type, and
9 8 amounts of all other revenues that the pharmacy benefits
9 9 manager receives from each pharmaceutical manufacturer or
9 10 labeler with whom the pharmacy benefits manager has a
9 11 contract. The bill specifies the information that the
9 12 pharmacy benefits manager is to disclose in writing, requires
9 13 the pharmacy benefits manager to provide the information
9 14 requested by the covered entity within 30 days of receipt of
9 15

9 16 the request, provides that the information is to be provided
9 17 no less than once each year, and requires that the contract
9 18 entered into between the pharmacy benefits manager and the
9 19 covered entity specify any fees to be charged for drug
9 20 utilization reports requested by the covered entity.
9 21 The bill prohibits a pharmacy benefits manager from
9 22 contacting a covered individual without the express written
9 23 permission of the covered entity, unless authorized pursuant
9 24 to the terms of its contract with a covered entity.
9 25 The bill provides that with the exception of utilization
9 26 information, a covered entity is required to maintain any
9 27 information disclosed in response to a request as confidential
9 28 and proprietary information and prohibits the covered entity
9 29 from using any such information for any other purpose or
9 30 disclosing such information to any other person except as
9 31 provided in the bill or in the contract between the pharmacy
9 32 benefits manager and the covered entity. The bill provides
9 33 that any covered entity that discloses information in
9 34 violation of the bill is subject to an action for injunctive
9 35 relief and is liable for any damages which are the direct and
10 1 proximate result of such disclosure. The bill provides that
10 2 the prohibition against disclosure of information provided
10 3 does not prohibit a covered entity from disclosing
10 4 confidential or proprietary information to the commissioner of
10 5 insurance, upon request, but also provides that any such
10 6 information obtained by the commissioner is confidential and
10 7 privileged and is not open to public inspection or disclosure.
10 8 The bill provides for auditing of the pharmacy benefits
10 9 manager, and provides that the pharmacy benefits manager may
10 10 request a substitution for a prescribed drug to a covered
10 11 individual, with certain limitations.
10 12 The bill provides that a covered entity may bring a civil
10 13 action to enforce the provisions of the bill or seek civil
10 14 damages for a violation of the bill. The bill provides that
10 15 the provisions of the bill apply only to pharmacy benefits
10 16 management services contracts entered into or renewed on or
10 17 after July 1, 2007.
10 18 LSB 1827HV 82
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