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SENATE FILE 181

BY CONNOLLY

HUMAN RESOURCES

Passed Senate, Date _____ Passed House, 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 for civil relief.

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

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SF 181 HUMAN RESOURCES

1 Section 1. NEW SECTION. 155B.1 DEFINITIONS.

2 As used in this chapter unless the context otherwise
3 requires:

4 1. "Commissioner" means the commissioner of insurance.

5 2. "Covered entity" means a nonprofit hospital or medical
6 services corporation, health insurer, health benefit plan, or
7 health maintenance organization; a health program administered
8 by the state in the capacity of provider of health coverage;
9 or an employer, labor union, or other group of persons
10 organized in the state that provides health coverage to
11 covered individuals who are employed or reside in the state.

12 "Covered entity" does not include a self-funded plan that is
13 exempt from state regulation pursuant to the federal Employee
14 Retirement Income Security Act of 1974 (ERISA), as codified at
15 29 U.S.C. § 1001 et seq., a plan issued for coverage for
16 federal employees, or a health plan that provides coverage
17 only for accidental injury, specified disease, hospital
18 indemnity, Medicare supplemental, disability income, long-
19 term care, or other limited benefit health insurance policies
20 and contracts.

21 3. "Covered individual" means a member, participant,
22 enrollee, contract holder, policyholder, or beneficiary of a
23 covered entity who is provided health coverage by the covered
24 entity. "Covered individual" includes a dependent or other
25 person provided health coverage through a policy, contract, or
26 plan for a covered individual.

27 4. "Generic drug" means a chemically equivalent copy of a
28 brand-name drug with an expired patent.

29 5. "Labeler" means an entity or person that receives
30 prescription drugs from a manufacturer or wholesaler and
31 repackages those drugs for later retail sale and that has a
32 labeler code from the federal food and drug administration
33 under 21 C.F.R. § 270.201.

34 6. "Pharmacy benefits management" means the procurement of
35 prescription drugs at a negotiated rate for dispensing within

1 this state to covered individuals, the administration or
2 management of prescription drug benefits provided by a covered
3 entity for the benefit of covered individuals, or any of the
4 following services provided with regard to the administration
5 of the following pharmacy benefits:

6 a. Mail service pharmacy.

7 b. Claims processing, retail network management, or
8 payment of claims to pharmacies for prescription drugs
9 dispensed to covered individuals.

10 c. Clinical formulary development and management services.

11 d. Rebate contracting and administration.

12 e. Certain patient compliance, therapeutic intervention,
13 or generic substitution programs.

14 f. Disease management programs involving prescription drug
15 utilization.

16 7. "Pharmacy benefits manager" means an entity that
17 performs pharmacy benefits management services. "Pharmacy
18 benefits manager" includes a person or entity acting for a
19 pharmacy benefits manager in a contractual or employment
20 relationship in the performance of pharmacy benefits
21 management services for a covered entity. "Pharmacy benefits
22 manager" does not include a health insurance carrier or its
23 subsidiary when the health insurance carrier or its subsidiary
24 is providing pharmacy benefits management services to its own
25 insureds; or a public self-funded pool or a private single
26 employer self-funded plan that provides such benefits or
27 services directly to its beneficiaries.

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

30 9. "Prescription drug order" means a written order from a
31 practitioner or an oral order from a practitioner or the
32 practitioner's authorized agent who communicates the
33 practitioner's instructions for a prescription drug or device
34 to be dispensed.

35 10. "Proprietary information" means information on

1 pricing, costs, revenue, taxes, market share, negotiating
2 strategies, customers, or personnel held by private entities
3 and used for that private entity's business purposes.

4 11. "Trade secret" means information, including a
5 formula, pattern, compilation, program, device, method,
6 technique, or process, that meets all of the following
7 conditions:

8 a. Derives independent economic value, actual or
9 potential, from not being generally known to, and not being
10 readily ascertainable by proper means by, other persons who
11 can obtain economic value from its disclosure or use.

12 b. Is the subject of efforts that are reasonable under the
13 circumstances to maintain its secrecy.

14 Sec. 2. NEW SECTION. 155B.2 PHARMACY BENEFITS MANAGER --
15 LICENSE.

16 1. A person shall not perform or act as a pharmacy
17 benefits manager in this state without obtaining an annual
18 license to do business in this state from the commissioner
19 under this section.

20 2. The commissioner shall adopt rules, pursuant to chapter
21 17A, relating to the issuance of a license under this section.
22 The rules shall include but are not limited to inclusion of
23 all of the following:

24 a. Definition of terms.

25 b. Use of prescribed forms.

26 c. Reporting requirements.

27 d. Enforcement procedures.

28 e. Protection of proprietary information and trade
29 secrets.

30 Sec. 3. NEW SECTION. 155B.3 MANAGER TO PERFORM DUTIES IN
31 GOOD FAITH.

32 Each pharmacy benefits manager shall perform its duties
33 exercising good faith and fair dealing toward the covered
34 entity and covered individuals.

35 Sec. 4. NEW SECTION. 155B.4 DISCLOSURE OF REVENUES

1 RECEIVED FROM PHARMACEUTICAL MANUFACTURER OR LABELER UNDER
2 CONTRACT WITH MANAGER -- CONTENT -- FEES.

3 1. A covered entity may request that any pharmacy benefits
4 manager with which it has a pharmacy benefits management
5 services contract disclose to the covered entity, the amount
6 of all rebate revenues and the nature, type, and amounts of
7 all other revenues that the pharmacy benefits manager receives
8 from each pharmaceutical manufacturer or labeler with whom the
9 pharmacy benefits manager has a contract. The pharmacy
10 benefits manager shall disclose all of the following in
11 writing:

12 a. The aggregate amount and, for a list of drugs to be
13 specified in the contract, the specific amount, of all rebates
14 and other retrospective utilization discounts received by the
15 pharmacy benefits manager, directly or indirectly, from each
16 pharmaceutical manufacturer or labeler that is earned in
17 connection with the dispensing of prescription drugs to
18 covered individuals of the health benefit plans issued by the
19 covered entity or for which the covered entity is the
20 designated administrator.

21 b. The nature, type, and amount of all other revenue
22 received by the pharmacy benefits manager directly or
23 indirectly from each pharmaceutical manufacturer or labeler
24 for any other products or services provided to the
25 pharmaceutical manufacturer or labeler by the pharmacy
26 benefits manager with respect to programs that the covered
27 entity offers or provides to its enrollees.

28 c. Any prescription drug utilization information requested
29 by the covered entity relating to covered individuals.

30 2. A pharmacy benefits manager shall provide the
31 information requested by the covered entity for such
32 disclosure within thirty days of receipt of the request. If
33 requested, the information shall be provided no less than once
34 each year. The contract entered into between the pharmacy
35 benefits manager and the covered entity shall specify any fees

1 to be charged for drug utilization reports requested by the
2 covered entity.

3 Sec. 5. NEW SECTION. 155B.5 PERMISSION OF ENTITY
4 REQUIRED TO CONTACT COVERED INDIVIDUAL -- EXCEPTION.

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

9 Sec. 6. NEW SECTION. 155B.6 CONFIDENTIALITY OF
10 INFORMATION -- INJUNCTION -- DAMAGES.

11 1. With the exception of utilization information, a
12 covered entity shall maintain any information disclosed in
13 response to a request pursuant to section 155B.4 as
14 confidential and proprietary information, and shall not use
15 such information for any other purpose or disclose such
16 information to any other person except as provided in this
17 chapter or in the pharmacy benefits management services
18 contract between the parties.

19 2. A covered entity that discloses information in
20 violation of this section is subject to an action for
21 injunctive relief and is liable for any damages which are the
22 direct and proximate result of such disclosure.

23 3. This section does not prohibit a covered entity from
24 disclosing confidential or proprietary information to the
25 commissioner, upon request. Any such information obtained by
26 the commissioner is confidential and privileged and is not
27 open to public inspection or disclosure.

28 Sec. 7. NEW SECTION. 155B.7 AUDITS OF MANAGER'S RECORDS.

29 1. A covered entity may have the pharmacy benefits
30 manager's records related to the rebates or other information
31 described in section 155B.4 audited, to the extent the
32 information relates directly or indirectly to such covered
33 entity's contract, in accordance with the terms of the
34 pharmacy benefits management services contract between the
35 parties. However, if the parties have not expressly provided

1 for audit rights and the pharmacy benefits manager has advised
2 the covered entity that other reasonable options are available
3 and subject to negotiation, the covered entity may have such
4 records audited as follows:

5 a. An audit may be conducted no more frequently than once
6 in each twelve-month period upon not less than thirty business
7 days' written notice to the pharmacy benefits manager.

8 b. The covered entity may select an independent firm to
9 conduct the audit, and the independent firm shall sign a
10 confidentiality agreement with the covered entity and the
11 pharmacy benefits manager ensuring that all information
12 obtained during the audit will be treated as confidential.
13 The firm may not use, disclose, or otherwise reveal any such
14 information in any manner or form to any person or entity
15 except as otherwise permitted under the confidentiality
16 agreement. The covered entity shall treat all information
17 obtained as a result of the audit as confidential, and may not
18 use or disclose such information except as may be otherwise
19 permitted under the terms of the contract between the covered
20 entity and the pharmacy benefits manager or if ordered by a
21 court of competent jurisdiction for good cause shown.

22 c. Any audit shall be conducted at the pharmacy benefits
23 manager's office where such records are located, during normal
24 business hours, without undue interference with the pharmacy
25 benefits manager's business activities, and in accordance with
26 reasonable audit procedures.

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

29 1. With regard to the dispensing of a substitute
30 prescription drug for a prescribed drug to a covered
31 individual, when the pharmacy benefits manager requests a
32 substitution, the following provisions shall apply:

33 a. The pharmacy benefits manager may request the
34 substitution of a lower-priced generic and therapeutically
35 equivalent drug for a higher-priced prescribed drug.

1 b. With regard to substitutions in which the substitute
2 drug's net cost is more for the covered individual or the
3 covered entity than the prescribed drug, the substitution
4 shall be made only for medical reasons that benefit the
5 covered individual.

6 2. If a substitution is being requested pursuant to this
7 section, the pharmacy benefits manager shall obtain the
8 approval of the prescribing health professional prior to the
9 substitution.

10 3. A pharmacy benefits manager shall not substitute an
11 equivalent drug product contrary to a prescription drug order
12 that prohibits a substitution.

13 Sec. 9. NEW SECTION. 155B.9 CIVIL ACTION -- ENFORCEMENT
14 OF CHAPTER -- DAMAGES.

15 A covered entity may bring a civil action to enforce the
16 provisions of this chapter or to seek civil damages for the
17 violation of the provisions of this chapter.

18 Sec. 10. NEW SECTION. 155B.10 APPLICATION OF CHAPTER TO
19 CERTAIN CONTRACTS.

20 The provisions of this chapter apply only to pharmacy
21 benefits management services contracts entered into or renewed
22 on or after July 1, 2005.

23 EXPLANATION

24 This bill provides for the regulation of pharmacy benefits
25 managers. The bill provides definitions, requires that a
26 pharmacy benefits manager in this state obtain an annual
27 license from the commissioner of insurance, and directs the
28 commissioner of insurance to adopt rules related to defining
29 of terms, use of prescribed forms, reporting requirements,
30 enforcement procedures, and protection of proprietary
31 information and trade secrets.

32 The bill requires pharmacy benefits managers to perform
33 their duties exercising good faith and fair dealing toward the
34 covered entity and covered individuals.

35 The bill provides that a covered entity may request that a

1 pharmacy benefits manager with which it has a pharmacy
2 benefits management services contract disclose to the covered
3 entity the amount of all rebate revenues and the nature, type,
4 and amounts of all other revenues that the pharmacy benefits
5 manager receives from each pharmaceutical manufacturer or
6 labeler with whom the pharmacy benefits manager has a
7 contract. The bill specifies the information that the
8 pharmacy benefits manager is to disclose in writing, requires
9 the pharmacy benefits manager to provide the information
10 requested by the covered entity within 30 days of receipt of
11 the request, provides that if requested, the information is to
12 be provided no less than once each year, and requires that the
13 contract entered into between the pharmacy benefits manager
14 and the covered entity specify any fees to be charged for drug
15 utilization reports requested by the covered entity.

16 The bill prohibits a pharmacy benefits manager from
17 contacting a covered individual without the express written
18 permission of the covered entity, unless authorized pursuant
19 to the terms of its contract with a covered entity.

20 The bill provides that with the exception of utilization
21 information, a covered entity is required to maintain any
22 information disclosed in response to a request as confidential
23 and proprietary information, and prohibits the covered entity
24 from using any such information for any other purpose or
25 disclosing such information to any other person except as
26 provided in the bill or in the pharmacy benefits management
27 services contract between the parties. The bill provides that
28 any covered entity who discloses information in violation of
29 the bill is subject to an action for injunctive relief and is
30 liable for any damages which are the direct and proximate
31 result of such disclosure. The bill provides that the
32 prohibition against disclosure of information provided does
33 not prohibit a covered entity from disclosing confidential or
34 proprietary information to the commissioner of insurance, upon
35 request, but also provides that any such information obtained

1 by the commissioner is confidential and privileged and is not
2 open to public inspection or disclosure.

3 The bill provides for auditing of the pharmacy benefits
4 manager's records to the extent the information included in
5 the records relates directly or indirectly to the covered
6 entity's contract.

7 The bill provides that a pharmacy benefits manager may
8 request a substitution for a prescribed drug to a covered
9 individual and provides certain limitations on the
10 substitution.

11 The bill provides that a covered entity may bring a civil
12 action to enforce the provisions of the bill or to seek civil
13 damages for a violation of the bill. The bill provides that
14 the provisions of the bill apply only to pharmacy benefits
15 management services contracts entered into or renewed on or
16 after July 1, 2005.

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