

Senate File 2071 - Introduced

SENATE FILE 2071
BY HATCH

A BILL FOR

1 An Act relating to prescription drug costs and practices and
2 making penalties applicable.

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

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DIVISION I

PHARMACY BENEFITS MANAGERS

Section 1. Section 510.21, Code 2009, is amended to read as follows:

510.21 Certificate of registration required.

1. A person shall not act as or represent oneself to be a third-party administrator in this state, other than an adjuster licensed in this state for the kinds of business for which the person is acting as a third-party administrator, unless the person holds a current certificate of registration as a third-party administrator issued by the commissioner of insurance. A certificate of registration as a third-party administrator is renewable every three years. Failure to hold a certificate subjects the third-party administrator to the sanctions set out in section 507B.7. The certificate shall be issued by the commissioner to a third-party administrator unless the commissioner, after due notice and hearing, determines that the third-party administrator is not competent, trustworthy, financially responsible, or of good personal and business reputation, or has had a previous application for an insurance license denied for cause within the preceding five years.

2. An application for registration shall be accompanied by a filing fee of one hundred dollars. After notice and hearing, the commissioner may impose any or all of the sanctions set out in section 507B.7, upon finding that either the third-party administrator violated any of the requirements of sections 510.12 through 510.20 and this section, or the third-party administrator is not competent, trustworthy, financially responsible, or of good personal and business reputation. In addition, if the third-party administrator is a pharmacy benefits manager as defined in section 510B.2, the commissioner may impose any or all of the sanctions set out in section 507B.7 upon finding that the pharmacy benefits manager has violated any provision of chapter 510B.

1 Sec. 2. Section 510B.1, subsection 7, Code 2009, is amended
2 by striking the subsection and inserting in lieu thereof the
3 following:

4 7. "*Pharmacy benefits management*" means the procurement
5 of prescription drugs at a negotiated rate for dispensing
6 within the state to covered individuals, the administration or
7 management of prescription drug benefits provided by a covered
8 entity for the benefit of covered individuals, or any of the
9 following services provided with regard to the administration
10 of pharmacy benefits:

11 a. Mail service pharmacy.

12 b. Claims processing or retail network management and
13 payment of claims to pharmacies for prescription drugs
14 dispensed to covered individuals.

15 c. Clinical formulary development and management services.

16 d. Rebate contracting and administration.

17 e. Certain patient compliance, therapeutic intervention, and
18 generic substitution programs.

19 f. Disease management programs.

20 Sec. 3. Section 510B.3, Code 2009, is amended to read as
21 follows:

22 **510B.3 Enforcement — rules — penalties.**

23 1. The commissioner shall enforce the provisions of this
24 chapter.

25 2. The commissioner shall adopt rules pursuant to chapter
26 17A to administer this chapter including rules relating to all
27 of the following:

28 a. Timely payment of pharmacy claims.

29 b. A process for adjudication of complaints and settlement
30 of disputes between a pharmacy benefits manager and a licensed
31 pharmacy related to pharmacy auditing practices, termination of
32 pharmacy agreements, and timely payment of pharmacy claims.

33 3. A violation of this chapter is subject to the sanctions
34 and penalties as specified in section 510.21.

1 Sec. 4. Section 510B.4, Code 2009, is amended to read as

2 follows:

3 **510B.4 Performance of duties — good faith — conflict of**
4 **interest — required practices.**

5 1. A pharmacy benefits manager shall perform the pharmacy
6 benefits manager's duties exercising good faith and fair
7 dealing in the performance of its contractual obligations
8 toward the covered entity.

9 2. A pharmacy benefits manager shall notify the covered
10 entity in writing of any activity, policy, practice ownership
11 interest, or affiliation of the pharmacy benefits manager
12 that directly or indirectly presents any conflict of interest
13 pursuant to the requirements of this chapter.

14 3. A pharmacy benefits manager owes a fiduciary duty to a
15 covered entity and shall discharge that duty in accordance with
16 the provisions of state and federal law.

17 4. A pharmacy benefits manager shall perform its duties with
18 care, skill, prudence, and diligence and in accordance with the
19 standards of conduct applicable to a fiduciary in an enterprise
20 of a like character and with like aims.

21 5. a. A pharmacy benefits manager shall provide to a
22 covered entity all financial and utilization information
23 requested by the covered entity relating to the provision of
24 benefits to covered individuals through that covered entity and
25 all financial and utilization information relating to services
26 to that covered entity.

27 b. A pharmacy benefits manager shall disclose to the covered
28 entity all financial terms and arrangements for remuneration
29 of any kind that apply between the pharmacy benefits manager
30 and any prescription drug manufacturer or labeler, including
31 but not limited to formulary management and drug switching
32 programs, educational support, claims processing and pharmacy
33 network fees that are charged from retail pharmacies and data
34 sales fees.

35 c. A pharmacy benefits manager disclosing information under
1 this subsection may designate that material as confidential.

2 Information designated as confidential by a pharmacy benefits
3 manager and disclosed to a covered entity under this subsection
4 shall not be disclosed by the covered entity to any person
5 without the consent of the pharmacy benefits manager, except
6 that disclosure may be made in a court filing under state law
7 governing deceptive trade practices or when authorized by state
8 law or ordered by a court for good cause shown or made in a
9 court filing under seal unless or until otherwise ordered by a
10 court.

11 d. Nothing in this subsection limits the authority of the
12 attorney general to investigate violations of this chapter.

13 Sec. 5. Section 510B.6, Code 2009, is amended to read as
14 follows:

15 **510B.6 Dispensing of substitute prescription drug for**
16 **prescribed drug — passing on payments or benefits.**

17 1. The following provisions shall apply when a pharmacy
18 benefits manager requests the dispensing of a substitute
19 prescription drug for a prescribed drug to a covered
20 individual:

21 a. The pharmacy benefits manager may request the
22 substitution of a lower priced generic and therapeutically
23 equivalent drug for a higher priced prescribed drug.

24 b. If the substitute drug's net cost to the covered
25 individual or covered entity exceeds the cost of the prescribed
26 drug, the substitution shall be made only for medical reasons
27 that benefit the covered individual.

28 2. A pharmacy benefits manager shall obtain the approval
29 of the prescribing practitioner prior to requesting any
30 substitution under this section.

31 3. A pharmacy benefits manager shall not substitute an
32 equivalent prescription drug contrary to a prescription drug
33 order that prohibits a substitution.

34 4. If a pharmacy benefits manager makes a substitution in
35 which the substitute drug's net cost to the covered individual
1 or covered entity exceeds the cost of the prescribed drug, the

2 pharmacy benefits manager shall disclose to the covered entity
3 the cost of both drugs and any benefit or payment directly
4 or indirectly accruing to the pharmacy benefits manager as a
5 result of the substitution.

6 5. The pharmacy benefits manager shall transfer in full
7 to the covered entity any benefit or payment received in any
8 form by the pharmacy benefits manager either as a result of
9 a prescription drug substitution under subsection 4 or as a
10 result of the pharmacy benefits manager substituting a lower
11 priced generic and therapeutically equivalent drug for a higher
12 priced prescribed drug.

13 6. A pharmacy benefits manager that derives any payment or
14 benefit for the dispensing of a prescription drug within the
15 state based on volume of sales for certain prescription drugs
16 or classes or brands of drugs within the state shall pass that
17 payment or benefit on in full to the covered entity.

18 Sec. 6. NEW SECTION. 510B.8 Market conduct review and
19 audit.

20 The commissioner may review compliance with this chapter by
21 pharmacy benefits managers through market conduct reviews and
22 audits, and may assess an annual fee proportional to the cost
23 to the division of insurance associated with conducting the
24 market conduct review and audit. A market conduct review and
25 audit shall be completed at least once every three years for
26 each pharmacy benefits manager certified in the state.

27 DIVISION II

28 SECTION 340B PRESCRIPTION DRUG PURCHASING

29 Sec. 7. LEGISLATIVE INTENT. It is the intent of the general
30 assembly to reduce prescription drug costs to the state by
31 ensuring maximum use of prescription drug pricing available
32 through section 340B of the federal Public Health Service Act.

33 Sec. 8. WORKGROUP AND REPORT.

34 1. The department of public health shall convene a
35 workgroup to study the feasibility of providing discounted
1 prescription drugs to the most vulnerable of Iowa's citizens

2 through the use of section 340B of the federal Public Health
3 Service Act, 42 U.S.C. § 256b (1999). The workgroup shall
4 include representatives of 340B hospitals, the corrections
5 system, the medical assistance program, low-income nonprofit
6 advocacy organizations, and a representative of federally
7 qualified health centers or a related federally qualified
8 health centers' association. The workgroup, in collaboration
9 with the department of public health, shall work with other
10 state agencies, representatives of state employees, and
11 representatives of health care providers and facilities in the
12 state to provide all of the following information:

13 a. Covered entities. A description of all health care
14 providers and facilities in the state potentially eligible for
15 designation as "covered entities" under section 340B, including
16 but not limited to all hospitals eligible as disproportionate
17 share hospitals; recipients of grants from the United States
18 public health service; federally qualified health centers;
19 federally qualified look-alikes; state-operated AIDS drug
20 assistance programs; Ryan White CARE Act Title I, Title II, and
21 Title III programs; tuberculosis, black lung, family planning,
22 and sexually transmitted disease clinics; hemophilia treatment
23 centers; public housing primary care clinics; and clinics for
24 homeless people.

25 b. Potential applications and benefits. A listing of
26 potential applications of section 340B and the potential
27 benefits to public, private, and third-party payors for
28 prescription drugs, including but not limited to:

29 (1) Application to inmates and employees in juvenile
30 correctional facilities, county jails, and state correctional
31 institutions.

32 (2) Maximizing the use of section 340B within state-funded
33 managed care plans.

34 (3) Including section 340B providers in state bulk
35 purchasing initiatives.

1 (4) Utilizing sole source contracts with section 340B

2 providers to furnish high-cost chronic care drugs.

3 c. Section 340B discounts. Discounts available through
4 section 340B contracts, including estimated cost savings to
5 the state as a result of retail markup avoidance, negotiated
6 subceiling prices, and coordination with the medical assistance
7 program in order to minimize costs to the program and to other
8 purchasers of prescription drugs.

9 d. Identification of resources. The resources available to
10 potential applicants for designation as covered entities for
11 the application process, establishing a section 340B program,
12 restructuring the health care system, or other methods of
13 lowering the cost of prescription drugs. The resources shall
14 include state and federal agencies and private philanthropic
15 grants to be used for the purposes of this section.

16 2. The workgroup shall report its findings to the governor
17 and the general assembly not later than December 15, 2010.

18 EXPLANATION

19 This bill relates to the cost of prescription drugs
20 including practices of pharmacy benefits managers and the
21 federal section 340B program.

22 Division I of the bill relates to pharmacy benefits
23 managers. Pharmacy benefits managers are considered
24 third-party administrators under current law, and the bill
25 provides that in addition to violations of law relating to
26 third-party administrators, if a pharmacy benefits manager
27 violates provisions of law relating to pharmacy benefits
28 managers, the sanctions and penalties applicable to third-party
29 administrators apply to such violations. The bill redefines
30 "pharmacy benefits management" to include specific services
31 including mail services pharmacy and specifies required
32 practices of pharmacy benefits managers including the fiduciary
33 duties, provision of financial and utilization information, and
34 disclosure of financial terms and arrangements for remuneration
35 between the pharmacy benefits manager and any prescription drug
1 manufacturer or labeler. The bill also requires a pharmacy

2 benefits manager to disclose payments or benefits to a pharmacy
3 benefits manager for substitution of prescription drugs, and to
4 transfer any payment or benefit to the covered entity that is
5 realized through substitution or based on volume of sales. The
6 bill also authorizes the commissioner of insurance to perform a
7 market conduct review and audit at least every three years for
8 each pharmacy benefits manager.

9 Division II of the bill relates to prescription drug
10 purchasing through section 340B of the federal Public Health
11 Services Act (the section 340B program). The bill provides
12 that it is the intent of the general assembly to reduce
13 prescription drug costs to the state by ensuring maximum use of
14 prescription drug pricing available through the section 340B
15 program and directs the department of public health to convene
16 a workgroup to study the feasibility of providing discounted
17 prescription drugs to the most vulnerable of Iowa's citizens
18 through the section 340B program. The bill specifies the
19 membership of the workgroup, and specifies the information the
20 workgroup is to provide regarding covered entities under the
21 section 340B program, potential applications and benefits,
22 section 340B discounts, and identification of resources. The
23 bill directs the workgroup to report its findings to the
24 governor and the general assembly no later than December 15,
25 2010.