House Study Bill 701 - Introduced

HOUSE FILE _____
BY (PROPOSED COMMITTEE
ON COMMERCE BILL BY
CHAIRPERSON PETERSEN)

A BILL FOR

An Act relating to prescription drug costs, purchasing, and other practices, and making penalties applicable.

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

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.

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

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

a. Mail service pharmacy.

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

c. Clinical formulary development and management services.

d. Rebate contracting and administration.

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

f. Disease management programs.

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

510B.3 Enforcement — rules — penalties.

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

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

a. Timely payment of pharmacy claims.

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

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

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

follows:

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

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

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

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

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

5. *a.* A pharmacy benefits manager shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity.

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

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

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

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

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

510B.6 Dispensing of substitute prescription drug for prescribed drug ── passing on payments or benefits.

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

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

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

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

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

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

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

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

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

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

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

DIVISION II

SECTION 340B PRESCRIPTION DRUG PURCHASING

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

Sec. 8. WORKGROUP AND REPORT.

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

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

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

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

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

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

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

(4) Utilizing sole source contracts with section 340B

providers to furnish high-cost chronic care drugs.

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

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

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

EXPLANATION

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

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

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

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