

FEB 23 2005
HUMAN RESOURCES

HOUSE FILE 386
BY FORD

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

A BILL FOR

1 An Act relating to fair market drug pricing including the
2 establishment of a prescription drug card program.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 386

1 Section 1. FAIR MARKET DRUG PRICING -- LEGISLATIVE

2 FINDINGS. The general assembly finds that:

3 1. In this time of economic difficulty, the state of Iowa
4 needs to maximize its financial resources in order to provide
5 the maximum amount of health care coverage possible for low-
6 income residents. Now more than ever, the state of Iowa needs
7 to lower the prices it pays for prescription drugs.

8 2. At the same time, approximately one in four Iowans is
9 uninsured or underinsured for prescription drug coverage, and
10 does not qualify for medical assistance. These uninsured or
11 underinsured Iowans pay excessive prices for prescription
12 drugs. In many cases, these excessive drug prices have the
13 effect of denying Iowans access to medically necessary care,
14 thereby threatening their health and safety.

15 3. Among these uninsured and underinsured Iowans, many
16 require repeated doctor or medical clinic appointments, with
17 their health having degenerated because they cannot afford the
18 drugs prescribed for them. Many are admitted to or treated at
19 hospitals each year because they cannot afford the drugs
20 prescribed for them that could have prevented the need for
21 hospitalization. Many others enter expensive institutional
22 care settings because they cannot afford the prescription
23 drugs that could have supported them outside of an
24 institution. In each of these circumstances, uninsured and
25 underinsured residents too often become medical assistance
26 recipients because of their inability to afford prescription
27 drugs. Therefore, helping secure lower drug prices for
28 uninsured and underinsured Iowans directly benefits and
29 supports the medical assistance program.

30 4. The state is the only agent that, as a practical
31 matter, can play an effective role as a market participant on
32 behalf of all Iowans who are uninsured, underinsured, or are
33 medical assistance program beneficiaries. The state already
34 provides drugs and acts as a prescription benefits manager for
35 a variety of programs, and should expand that role to

1 negotiate voluntary drug rebates, using these funds to
2 maintain and expand medical assistance services while offering
3 lower drug prices to the uninsured who do not qualify for
4 medical assistance.

5 Sec. 2. NEW SECTION. 249A.35 FAIR MARKET DRUG PRICING
6 PROGRAM.

7 1. PURPOSE. Recognizing that the state already acts as a
8 prescription benefits manager for a variety of health plans
9 and assistance programs, the purpose of this section is to
10 provide prescription drug coverage to new populations by
11 expanding the state's role as a participant in the
12 prescription drug marketplace, negotiating voluntary rebates
13 from drug companies, and using the funds to make prescription
14 drugs more affordable to the state medical assistance program
15 and to Iowans. Such a program will improve public health and
16 welfare, promote the economic strength of our society, and
17 both directly and indirectly benefit the state medical
18 assistance program.

19 2. DEFINITIONS. As used in this section, unless the
20 context otherwise requires:

21 a. "Federal poverty level" means the federal poverty level
22 as defined by the most recently revised poverty income
23 guidelines published by the United States department of health
24 and human services.

25 b. "Labeler" means a person that receives prescription
26 drugs from a manufacturer or wholesaler and repackages those
27 drugs for later retail sale, and that has a labeler code from
28 the federal food and drug administration under 21 C.F.R. §
29 270.20.

30 c. "Manufacturer" means a manufacturer of prescription
31 drugs as defined in 42 U.S.C. § 1396r-8(k)(5), including a
32 subsidiary or affiliate of a manufacturer.

33 d. "Participating retail pharmacy" means a retail pharmacy
34 or other business licensed to dispense prescription drugs in
35 this state that participates in the state medical assistance

1 program, or voluntarily agrees to participate in the
2 prescription card program.

3 e. "Wholesaler" means wholesaler as defined in section
4 155A.3.

5 3. DRUG DISCOUNT AND REBATE AGREEMENTS.

6 a. In addition to negotiating rebates with drug
7 manufacturers pursuant to section 249A.20A, the director shall
8 negotiate other discount prices or rebates for prescription
9 drugs from drug manufacturers and labelers for the
10 prescription card program and other state programs that pay
11 for or acquire prescription drugs. A drug manufacturer or
12 labeler that sells prescription drugs in this state may
13 voluntarily elect to negotiate any of the following:

14 (1) Supplemental rebates for the medical assistance
15 program over and above those required under 42 U.S.C. § 1396r-
16 8 as provided in section 249A.20A.

17 (2) Discount prices or rebates for the prescription card
18 program.

19 (3) Discount prices or rebates for any other state program
20 that pays for or acquires prescription drugs.

21 b. In negotiating discount prices and rebate terms, the
22 director shall take into consideration the rebate calculated
23 under the medical assistance rebate program pursuant to 42
24 U.S.C. § 1396r-8, any rebate negotiated pursuant to section
25 249A.20A, the price provided to eligible entities under 42
26 U.S.C. § 256b, and any other available information on
27 prescription drug prices, discounts, and rebates.

28 c. (1) The director shall determine whether to include
29 the products in the formularies or prior authorization
30 programs for any state program that pays for or acquires
31 prescription drugs, taking into consideration the following:

32 (a) The director and a drug manufacturer or labeler fail
33 to reach agreement on the terms of a supplemental rebate under
34 the medical assistance program or a discount or rebate for the
35 prescription card program.

1 (b) The discounts or rebates offered by the manufacturer
2 or labeler are not as favorable to the state as the prices
3 provided to eligible entities under 42 U.S.C. § 256b.

4 (2) The names of manufacturers and labelers that do not
5 enter into discount pricing or rebate agreements under this
6 section are public information and the department shall
7 release this information to the public and actively distribute
8 the information to doctors, pharmacists, and other health
9 professionals.

10 4. PRESCRIPTION CARD PROGRAM ESTABLISHED.

11 a. The department shall establish the prescription card
12 program as a state pharmaceutical assistance program under 42
13 U.S.C. § 1396r-8(c)(1)(C), to provide discounts to
14 participants for drugs covered by a rebate agreement. Using
15 funds from negotiated rebates, the department shall contract
16 with wholesalers and participating retail pharmacies to
17 deliver discounted prices to prescription card participants.

18 b. The drug discounts received by prescription card
19 participants shall be calculated by the director on a
20 quarterly basis. That calculation shall provide discounts
21 approximately equal to the average amount of the negotiated
22 drug rebate minus an amount to cover the reasonable
23 administrative costs of the prescription card program.

24 c. (1) An individual is eligible to participate in the
25 prescription card program if the individual is a resident of
26 Iowa and is eligible for participation in the Medicare program
27 or has a net family income below three hundred fifty percent
28 of the federal poverty level.

29 (2) An individual is ineligible to participate in the
30 prescription card program if the individual is eligible for
31 assistance under the medical assistance program or is covered
32 by an insurance policy that provides benefits for prescription
33 drugs equal to or greater than the benefits provided under the
34 prescription card program, as specified by rules adopted by
35 the director.

1 d. The department shall establish simple procedures for
2 enrolling prescription card participants and shall undertake
3 outreach efforts to build public awareness of the program and
4 maximize enrollment by eligible residents.

5 e. (1) The department shall adopt rules requiring
6 disclosure by participating retail pharmacies to prescription
7 card program participants of the amount of savings provided as
8 a result of the prescription card program. The rules shall
9 include provisions to protect information that is proprietary
10 in nature.

11 (2) A participating retail pharmacy shall verify to the
12 department the amounts charged to prescription card
13 participants and nonparticipants, and shall provide the
14 department with utilization data necessary to calculate
15 rebates from manufacturers and labelers. The department shall
16 protect the confidentiality of all information subject to
17 confidentiality protection under state or federal law, rule,
18 or regulation. The department shall not impose transaction
19 charges on wholesalers or participating retail pharmacies that
20 submit claims or receive payments under the program.

21 (3) Wholesalers and participating retail pharmacies shall
22 be paid in advance for prescription card discounts or shall be
23 reimbursed by the department on a bi-weekly basis.

24 f. The department may require a wholesaler or
25 participating retail pharmacy to segregate drugs under the
26 prescription card program from other drug inventory. The
27 department may require a wholesaler or participating retail
28 pharmacy to maintain records of acquisition and disposition of
29 drugs under the prescription card program separately from the
30 wholesaler's or pharmacy's other records.

31 g. Disputes or discrepancies in rebate amounts shall be
32 resolved using the following process:

33 (1) If there is a discrepancy in the manufacturer's or
34 labeler's favor between the amount claimed by a pharmacy and
35 the amount rebated by the manufacturer or labeler, the

1 department, at the department's expense, may hire a mutually
2 agreed upon independent auditor. If a discrepancy still
3 exists following the audit, the manufacturer or labeler shall
4 justify the reason for the discrepancy or make payment to the
5 department for any additional amount due.

6 (2) If there is a discrepancy against the interest of the
7 manufacturer or labeler in the information provided by the
8 department to the manufacturer or labeler regarding the
9 manufacturer's or labeler's rebate, the manufacturer or
10 labeler, at the manufacturer's or labeler's expense, may hire
11 a mutually agreed upon independent auditor to verify the
12 accuracy of the data supplied to the department. If a
13 discrepancy still exists following the audit, the department
14 shall justify the reason for the discrepancy or provide a
15 refund to the manufacturer or labeler.

16 (3) Following the procedures established in subparagraph
17 (1) or (2), either the department or the manufacturer or
18 labeler may request a hearing. Supporting documentation shall
19 accompany the request for a hearing.

20 h. Discounts to participants in the prescription card
21 program shall begin no later than January 1, 2006.

22 5. ADMINISTRATION.

23 a. The department shall report the enrollment and
24 financial status of the prescription card program and report
25 savings from any supplemental medical assistance program
26 rebates and any other discounts or rebates to the general
27 assembly by February 1, annually.

28 b. If the director determines that it is beneficial to
29 both the prescription card program and another state program
30 to combine drug pricing negotiations to maximize discount
31 pricing and drug rebates, the director shall work with the
32 other state program to do so.

33 c. The department shall adopt rules to implement this
34 section.

35 d. The department shall seek any waivers of federal law,

1 rule, or regulation necessary to implement the provisions of
2 this section.

3 e. The department shall administer this section in a
4 manner that benefits the greatest number of residents while
5 remaining in compliance with federal law and regulations. If
6 necessary, the director may separate medical assistance
7 program negotiations from nonmedical assistance program
8 negotiations and preferred drug list decisions, or may limit
9 participation in the prescription card program to reduce the
10 number of participants.

11 6. MEDICAL ASSISTANCE WAIVER DISCOUNT PLAN. In addition
12 to the prescription card program established in this section,
13 the department shall seek a section 1115 Medicaid waiver from
14 the centers for Medicaid and Medicare services of the United
15 States department of health and human services to establish a
16 pharmacy discount program modeled after the healthy Maine
17 prescriptions program. If the waiver is approved, the
18 department shall implement the program following consultation
19 with the legislative government oversight committee.

20 EXPLANATION

21 This bill directs the director of human services, in
22 addition to negotiating rebates with drug manufacturers
23 pursuant to the Medicaid preferred drug list program, to
24 negotiate other discount prices or rebates for prescription
25 drugs from drug manufacturers and labelers for the
26 prescription card program and other state programs that pay
27 for or acquire prescription drugs.

28 The bill provides that the director is to determine whether
29 to include the products of labelers and manufacturers in the
30 formularies or prior authorization programs for any state
31 program that pays for or acquires prescription drugs, taking
32 into consideration: (a) if the director and a drug
33 manufacturer or labeler fail to reach agreement on the terms
34 of a supplemental rebate under the medical assistance program
35 or a discount or rebate for the prescription card program; or

1 (b) whether the discounts or rebates offered by the
2 manufacturer or labeler are not as favorable to the state as
3 the prices provided to eligible entities under 42 U.S.C. §
4 256b. The bill also provides that the names of manufacturers
5 and labelers that do not enter into discount pricing or rebate
6 agreements are public information and the department of human
7 services is to release this information to the public and
8 actively distribute the information to doctors, pharmacists,
9 and other health professionals.

10 The bill establishes the prescription card program as a
11 state pharmaceutical assistance program to provide discounts
12 to participants for drugs covered by a rebate agreement.
13 Using funds from negotiated rebates, the department is
14 directed to contract with wholesalers and participating retail
15 pharmacies to deliver discounted prices to prescription card
16 participants. An individual is eligible to participate in the
17 prescription card program if the individual is a resident of
18 Iowa and is eligible for participation in the Medicare program
19 or has a net family income below 350 percent of the federal
20 poverty level. An individual is ineligible to participate in
21 the prescription card program if the individual is eligible
22 for assistance under the medical assistance program or is
23 covered by an insurance policy that provides benefits for
24 prescription drugs equal to or greater than the benefits
25 provided under the prescription card program. The bill
26 directs the department to establish simple procedures for
27 enrolling prescription card participants and to undertake
28 outreach efforts to build public awareness of the program and
29 maximize enrollment by eligible residents. The bill directs
30 the department to adopt rules requiring disclosure by
31 participating retail pharmacies to prescription card program
32 participants of the amount of savings provided as a result of
33 the prescription card program. The rules are to include
34 provisions to protect information that is proprietary in
35 nature. The bill specifies requirements for participating

1 retail pharmacies and wholesalers, provides for payment of
2 wholesalers and participating retail pharmacies, and provides
3 a process for addressing discrepancies or disputes in rebate
4 amounts. The bill provides that discounts to participants in
5 the prescription card program are to begin no later than
6 January 1, 2006.

7 The bill directs the department to report the enrollment
8 and financial status of the prescription card program and
9 report savings from any supplemental medical assistance
10 program rebates and any other discounts or rebates to the
11 general assembly by February 1, annually; provides that if the
12 director determines that it is beneficial to both the
13 prescription card program and another state program to combine
14 drug pricing negotiations to maximize discount pricing and
15 drug rebates, the director shall work with the other state
16 program to do so; directs the department to adopt rules to
17 implement the provisions of the bill; directs the department
18 to seek any waivers of federal law, rule, or regulation
19 necessary to implement the provisions of the bill; directs the
20 department to administer the bill in a manner that benefits
21 the greatest number of residents while remaining in compliance
22 with federal law and regulation; and provides that if
23 necessary, the director may separate medical assistance
24 program negotiations from nonmedical assistance program
25 negotiations and preferred drug list decisions, or may limit
26 participation in the prescription card program to reduce the
27 number of participants.

28 The bill also directs the department to seek a Medicaid
29 waiver from the centers for Medicaid and Medicare services of
30 the United States department of health and human services to
31 establish a pharmacy discount program modeled after the
32 healthy Maine prescriptions program. If the waiver is
33 approved, the bill directs the department to implement the
34 program following consultation with the legislative government
35 oversight committee.