

JAN 31 2002
HUMAN RESOURCES

HOUSE FILE 2177
BY OSTERHAUS

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

A BILL FOR

1 An Act relating to the establishment of a medical assistance
2 preferred drug formulary spending control program.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 2177

1 Section 1. NEW SECTION. 249A.20A PREFERRED DRUG
2 FORMULARY SPENDING CONTROL PROGRAM.

3 1. The department shall establish and implement a
4 preferred drug formulary spending control program applicable
5 to the provision of medical assistance in accordance with this
6 section.

7 2. a. A medical assistance pharmaceutical and
8 therapeutics committee is created within the department for
9 the purpose of developing a preferred drug formulary pursuant
10 to 42 U.S.C. § 1396r-8.

11 b. The committee shall be comprised as specified in 42
12 U.S.C. § 1396r-8 and shall consist of eleven members appointed
13 by the governor. Four members shall be physicians, licensed
14 pursuant to chapter 148 or 150A, five members shall be
15 pharmacists licensed pursuant to chapter 155A, one member
16 shall be a consumer representative, and one member shall
17 represent the interests of pharmaceutical manufacturers. A
18 portion of the appointees shall include representatives of
19 medical assistance program participating physicians and
20 pharmacists who have experience in either developing or
21 practicing under a preferred drug formulary.

22 c. The members shall be appointed to terms of two years.
23 Members may be appointed to more than one term. The
24 department shall provide staff for the committee.

25 d. Committee members shall select a chairperson and a vice
26 chairperson annually from the committee membership.

27 e. The committee shall meet at least quarterly and may
28 meet at other times at the discretion of the chairperson.

29 3. a. The committee shall recommend a preferred drug
30 formulary to the department established in accordance with 42
31 U.S.C. § 1396r-8. The committee shall develop the preferred
32 drug formulary recommendations by considering the drug's
33 clinically meaningful therapeutic advantage in terms of
34 safety, effectiveness, or clinical outcome.

35 b. The department shall adopt by rule a preferred drug

1 formulary applicable to the provision of medical assistance
2 based upon the recommendations of the committee.

3 c. To the extent possible, the committee shall review all
4 drug classes included in the formulary at least every twelve
5 months, and may recommend additions to and deletions from the
6 formulary, so that the formulary provides for medically
7 appropriate drug therapies for medical assistance recipients
8 and achieves cost savings to the medical assistance program.

9 4. a. The department may negotiate supplemental rebates
10 from manufacturers that are in addition to those required by
11 Title XIX of the federal Social Security Act and at no less
12 than ten percent of the average manufacturer price as defined
13 in 42 U.S.C. § 1396r-8(k)(1) on the last day of a quarter,
14 unless the federal or supplemental rebate, or both, equals or
15 exceeds twenty-five percent. An upper limit on the
16 supplemental rebates the department may negotiate shall not be
17 established.

18 b. The department may determine that specific products,
19 brand-name or generic, are competitive at lower rebate
20 percentages. Agreement to pay the minimum supplemental rebate
21 percentage shall guarantee a manufacturer that the committee
22 will consider a product for inclusion on the preferred drug
23 formulary. However, a pharmaceutical manufacturer is not
24 guaranteed placement on the formulary simply by paying the
25 minimum supplemental rebate.

26 c. The department may contract with an outside entity or
27 contractor to conduct negotiations for supplemental rebates.

28 d. For the purposes of this subsection, the term
29 "supplemental rebates" may include, at the department's
30 discretion, cash rebates and other program benefits that
31 offset a medical assistance expenditure. The program benefits
32 may include, but are not limited to, disease management
33 programs, drug product donation programs, drug utilization
34 control programs, prescriber and beneficiary counseling and
35 education, fraud and abuse initiatives, and other services or

1 administrative investments with guaranteed savings to the
2 medical assistance program.

3 5. With the exception of mental health-related drugs,
4 antiretroviral drugs, and drugs for health care facility
5 residents, reimbursement of drugs not included in the
6 formulary is subject to prior authorization.

7 6. The department shall publish and disseminate the
8 preferred drug formulary to all medical assistance providers
9 in the state.

10 7. The committee shall ensure that pharmaceutical
11 manufacturers agreeing to provide a supplemental rebate as
12 provided in this section have an opportunity to present
13 evidence supporting inclusion of a product on the preferred
14 drug formulary. Upon timely notice, the department shall
15 ensure that any drug that has been approved or had any of its
16 particular uses approved by the United States food and drug
17 administration under a priority review classification will be
18 reviewed by the committee at the next regularly scheduled
19 meeting. To the extent possible, upon notice by a
20 manufacturer, the department shall also schedule a product
21 review for any new product at the next regularly scheduled
22 meeting.

23 8. The committee may also make recommendations to the
24 department regarding the prior authorization of any prescribed
25 drug covered under the medical assistance program.

26 9. The department shall seek any federal waivers necessary
27 to implement this program.

28 EXPLANATION

29 This bill directs the department of human services to
30 establish and implement a preferred drug formulary spending
31 control program applicable to the provision of medical
32 assistance. The bill creates the medical assistance
33 pharmaceutical and therapeutics committee, within the
34 department, to develop a preferred drug formulary in
35 accordance with federal law. The committee is comprised of 11

1 members appointed by the governor. Four members are to be
2 physicians, five members are to be pharmacists, one member is
3 to be a consumer representative, and one member is to be a
4 representative of the interests of pharmaceutical
5 manufacturers. A portion of the appointees is to include
6 representatives of medical assistance program participating
7 physicians and pharmacists. The bill provides procedural
8 requirements for the committee.

9 The committee is directed to recommend a preferred drug
10 formulary to the department in accordance with federal law.
11 The recommendations are to be developed by the committee
12 considering the drug's clinically meaningful therapeutic
13 advantage in terms of safety, effectiveness, or clinical
14 outcome. The bill directs the department to adopt by rule a
15 preferred drug formulary applicable to the provision of
16 medical assistance based upon the recommendations of the
17 committee. The bill directs the committee, to the extent
18 possible, to review all drug classes included in the formulary
19 at least every 12 months, and to recommend additions to and
20 deletions from the formulary.

21 The bill authorizes the department to negotiate
22 supplemental rebates from manufacturers that are in addition
23 to those required by Title XIX of the federal Social Security
24 Act based upon a rebate percentage. Under the bill, an
25 agreement to pay the minimum supplemental rebate percentage
26 guarantees a manufacturer that the committee will consider a
27 product for inclusion on the preferred drug formulary, but a
28 manufacturer is not guaranteed placement on the formulary
29 solely by paying the minimum supplemental rebate.
30 "Supplemental rebate" may include cash rebates and other
31 program benefits such as disease management programs, drug
32 product donation programs, drug utilization control programs,
33 prescriber and beneficiary counseling and education, fraud and
34 abuse initiatives, and other services or administrative
35 investments with guaranteed savings to the medical assistance

1 program. The bill authorizes the department to contract with
2 an outside entity or contractor to conduct negotiations for
3 supplemental rebates. The bill provides that with few
4 exceptions, reimbursement of drugs not included in the
5 formulary is subject to prior authorization.

6 The bill directs the department to seek any federal waivers
7 necessary to implement the program, and provides that the
8 committee may also make recommendations to the department
9 regarding the prior authorization of any prescribed drug
10 covered under the medical assistance program.

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