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COMMERCE AND REGULATION

HOUSE FILE 2161  
BY GRUNDBERG

Passed House, Date \_\_\_\_\_ Passed Senate, Date \_\_\_\_\_  
Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_ Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_  
Approved \_\_\_\_\_

**A BILL FOR**

1 An Act relating to third-party payor coverage for prescription  
2 drugs, including off-label use of prescription drugs.  
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 2161

1 Section 1. NEW SECTION. 514C.21 COVERAGE FOR OFF-LABEL  
2 USE OF PRESCRIPTION DRUGS.

3 1. For the purposes of this section, unless the context  
4 otherwise requires:

5 a. "FDA" means the United States food and drug  
6 administration.

7 b. "Off-label" means the use of an FDA-approved drug for  
8 an indication that is not included in the approved labeling.

9 c. "Peer-reviewed medical literature" means published  
10 scientific studies in any peer-reviewed national professional  
11 medical journal.

12 d. "Standard reference compendium" means any of the  
13 following:

14 (1) The American hospital formulary service drug  
15 information.

16 (2) The American medical association drug evaluation.

17 (3) The United States pharmacopeia drug information.

18 2. Notwithstanding section 514C.6, a policy or contract  
19 providing for third-party payment or prepayment of health care  
20 or medical expenses that provides benefits for prescription  
21 drugs shall include a provision for the payment of off-label  
22 prescription drugs, if all of the following conditions are  
23 met:

24 a. The drug is approved for use by the United States food  
25 and drug administration.

26 b. The drug is prescribed by a licensed health care  
27 provider, participating under the policy or contract, for  
28 appropriate medical treatment.

29 c. The drug has been recognized for the medical treatment  
30 for which the drug is prescribed in at least one standard  
31 reference compendium or in at least one article from peer-  
32 reviewed medical literature.

33 3. Coverage for a prescription drug under this section  
34 also includes medically necessary services associated with the  
35 administration of the drug.

1 4. This section shall not be construed to require any of  
2 the following:

3 a. Coverage for any experimental drug not otherwise  
4 approved for the proposed use by the United States food and  
5 drug administration.

6 b. Coverage for any disease, condition, service, or  
7 treatment that is excluded from coverage.

8 5. This section shall not be construed to reduce or limit  
9 coverage for off-label use of drugs otherwise required by law  
10 or contract.

11 6. If requested by a third-party payor, a participating  
12 health care provider shall submit documentation as described  
13 in subsection 2, paragraph "c".

14 7. This section applies to the following classes of third-  
15 party payment provider contracts or policies delivered, issued  
16 for delivery, continued, or renewed in this state on or after  
17 January 1, 2003:

18 a. Individual or group accident and sickness insurance  
19 providing coverage on an expense-incurred basis.

20 b. An individual or group hospital or medical service  
21 contract issued pursuant to chapter 509, 514, or 514A.

22 c. An individual or group health maintenance organization  
23 contract regulated under chapter 514B.

24 d. An individual or group Medicare supplemental policy,  
25 unless the coverage required by this section pursuant to such  
26 a policy is preempted by federal law.

27 e. An organized delivery system licensed by the director  
28 of public health.

29 f. Any other entity engaged in the business of insurance,  
30 risk transfer, or risk retention, which is subject to the  
31 jurisdiction of the commissioner.

32 Sec. 2. NEW SECTION. 514C.22 OVERRIDING FORMULARY  
33 RESTRICTIONS.

34 1. Notwithstanding section 514C.6, a policy or contract  
35 providing for third-party payment or prepayment of health care

1 or medical expenses that provides benefits for prescription  
2 drugs shall include a provision that allows a prescribing  
3 licensed health care provider to override any formulary  
4 restrictions if the health care provider determines that the  
5 prescription drug prescribed is medically necessary for the  
6 benefit of the patient. The procedure for overriding the  
7 formulary may include peer review, but shall not impose  
8 additional administrative requirements on the prescribing  
9 health care provider.

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EXPLANATION

11 This bill provides that a policy or contract providing for  
12 third-party payment or prepayment of health care or medical  
13 expenses that provides benefits for prescription drugs shall  
14 include a provision for the payment of off-label prescription  
15 drugs, if the drug is approved for use by the United States  
16 food and drug administration (FDA); the drug is prescribed by  
17 a licensed health care provider, participating under the  
18 policy or contract, for appropriate medical treatment; and the  
19 drug has been recognized for the medical treatment for which  
20 it was prescribed in at least one standard reference  
21 compendium or in at least one article from peer-reviewed  
22 medical literature. Required coverage for a prescription drug  
23 also includes medically necessary services associated with the  
24 administration of the drug. The bill does not require  
25 coverage for any experimental drug not otherwise approved by  
26 the FDA for the proposed use or coverage for any disease,  
27 condition, service, or treatment that is excluded from  
28 coverage. The bill is not to be construed to reduce or limit  
29 coverage for off-label use of drugs otherwise required by law  
30 or contract. The bill provides that if a third-party payor  
31 requests, the participating health care provider who  
32 prescribes the off-label drug is to submit documentation that  
33 the drug has been recognized for the medical treatment for  
34 which it was prescribed in at least one standard reference  
35 compendium or in at least one article from peer-reviewed

1 medical literature.

2 The required coverage applies to third-party payment  
3 provider contracts or policies delivered, issued for delivery,  
4 continued, or renewed in this state on or after January 1,  
5 2003, that include individual or group accident and sickness  
6 insurance providing coverage on an expense-incurred basis; an  
7 individual or group hospital or medical service contract  
8 issued pursuant to Code chapter 509, 514, or 514A; an  
9 individual or group health maintenance organization contract  
10 regulated under Code chapter 514B; an individual or group  
11 Medicare supplemental policy, unless the coverage required by  
12 this section pursuant to such a policy is preempted by federal  
13 law; an organized delivery system licensed by the director of  
14 public health; and any other entity engaged in the business of  
15 insurance, risk transfer, or risk retention, which is subject  
16 to the jurisdiction of the commissioner.

17 The bill also provides that a policy or contract providing  
18 for third-party payment or prepayment of health care or  
19 medical expenses that provides benefits for prescription drugs  
20 shall include a provision that allows a prescribing licensed  
21 health care provider to override any formulary restrictions if  
22 the health care provider determines that the prescription drug  
23 prescribed is medically necessary for the benefit of the  
24 patient. The bill provides that the procedure for overriding  
25 the formulary may include peer review but is not to impose  
26 additional administrative requirements on the prescribing  
27 health care provider.

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