

SENATE FILE 423
BY HOLVECK

Passed Senate, Date _____ Passed House, 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:

SF 423
COMMERCE

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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. "Off-label" means the use of a drug approved by the
6 United States food and drug administration for an indication
7 that is not included in the approved labeling.

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

11 c. "Standard reference compendium" means any of the
12 following:

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

15 (2) The American medical association drug evaluation.

16 (3) The United States pharmacopoeia drug information.

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

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

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

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

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

35 4. This section shall not be construed to require any of

1 the following:

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

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

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

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

13 7. This section applies to the following classes of third-
14 party payment provider contracts or policies delivered, issued
15 for delivery, continued, or renewed in this state on or after
16 January 1, 2004:

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

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

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

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

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

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

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

33 Notwithstanding section 514C.6, a policy or contract
34 providing for third-party payment or prepayment of health care
35 or medical expenses that provides benefits for prescription

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

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EXPLANATION

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

1 The required coverage applies to third-party payment
2 provider contracts or policies delivered, issued for delivery,
3 continued, or renewed in this state on or after January 1,
4 2004, that include individual or group accident and sickness
5 insurance providing coverage on an expense-incurred basis; an
6 individual or group hospital or medical service contract
7 issued pursuant to Code chapter 509, 514, or 514A; an
8 individual or group health maintenance organization contract
9 regulated under Code chapter 514B; an individual or group
10 Medicare supplemental policy, unless the coverage required by
11 this section pursuant to such a policy is preempted by federal
12 law; an organized delivery system licensed by the director of
13 public health; and any other entity engaged in the business of
14 insurance, risk transfer, or risk retention, which is subject
15 to the jurisdiction of the commissioner.

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

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