HSB 243

HUMAN RESOURCES

Hodgett
Boddicker
Taylor

HOUSE FILE _____

BY (PROPOSED COMMITTEE ON HUMAN RESOURCES BILL BY CHAIRPERSON BODDICKER)

Passed House, Date _____ Passed Senate, Date _____

Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____

Approved _____

A BILL FOR

An Act relating to third-party payor coverage for off-label use of prescription drugs.

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

TLSB 2180HC 78

mj/cf/24

S.F. [redacted] H.F. _____

Section 1. LEGISLATIVE FINDINGS. The Iowa general assembly finds and declares all of the following:

1. Third-party payors have denied payment for prescription drugs that have been approved by the United States food and drug administration, when the drugs are prescribed for uses other than those stated on the marketing label approved by the United States food and drug administration, while other insurers with similar coverage terms do pay for off-label use. Denial of payment for off-label uses interrupts necessary and appropriate treatment for persons being treated for life-threatening illnesses by competent, responsible medical professionals.

2. The United States food and drug administration and the United States department of health and human services recognize the wide variety of effective uses of federally approved drugs through off-label uses. Continuing medical research has demonstrated effective, new uses of federally approved drugs. Information on the appropriate off-label use of federally approved drugs is obtained from compendia published by the United States pharmacopeial convention or the American society of hospital pharmacists. In addition, scientific studies of off-label use of drugs published in recognized peer-reviewed professional journals provide information on appropriate off-label uses of drugs. The federal Omnibus Budget Reconciliation Act of 1990 recognizes these compendia and peer-reviewed literature as appropriate sources for reimbursement.

3. The federal approval process for drugs is very expensive and time-consuming. Use of federally approved drugs for off-label uses provides efficacious drugs at a lower cost. To require that all appropriate uses of a drug undergo approval by the United States food and drug administration would substantially increase the cost of drugs, and delay or deny patients' ability to obtain medically effective treatment. To require approval for all new uses would add to

the already rising cost of prescription drugs.

4. Reimbursement for off-label uses of federally approved drugs is necessary to conform to the way in which appropriate medical treatment is provided, to make needed drugs available to patients, and to contain health care costs.

Sec. 2. NEW SECTION. 514C.141 COVERAGE FOR OFF-LABEL USE OF PRESCRIPTION DRUGS.

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

a. "Medical literature" means published scientific studies published in any peer-reviewed national professional journal of medicine.

b. "Standard reference compendia" means any of the following:

(1) The United States pharmacopoeia drug information.

(2) The American hospital formulary service drug information.

(3) Drugdex.

2. Notwithstanding section 514C.6, a policy or contract providing for third-party payment or prepayment of health care or medical expenses shall not exclude coverage for a prescription drug for a particular use on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the United States food and drug administration, provided that all the following conditions have been met:

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

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

c. The drug has been recognized for the medical treatment for which it was prescribed by one of the following:

(1) The American hospital formulary service drug information.

(2) The United States pharmacopoeia dispensing information.

(3) One article from a major peer-reviewed medical journal that presents data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

3. A participating health care provider, if requested by a third-party payor, shall submit to the third-party payor documentation as identified in subsection 1, paragraph "c".

4. Coverage for a drug pursuant to this section also includes medically necessary services associated with the administration of the drug.

5. This section applies to the following classes of third-party payment provider contracts or policies delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2000:

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

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

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

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

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

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

6. a. This section shall not be construed to alter existing laws with regard to provisions limiting the coverage of drugs that have not been approved by the United States food and drug administration.

b. This section shall not be construed to require coverage for experimental drugs not otherwise approved for any use by the United States food and drug administration.

c. This section shall not reduce or limit coverage for off-label use of drugs otherwise required by law or contract.

7. The commissioner shall create a panel of seven experts to review off-label uses not included in any of the two standard reference compendia or in the medical literature and to give advice to the commissioner in such instances as to whether a particular off-label use is medically appropriate. The panel shall make such recommendations from time to time and whenever a dispute about payment for an off-label use is brought to the commissioner. The seven-member panel shall include all of the following:

a. Three physicians licensed in this state as follows:

(1) One selected by the state medical oncology association.

(2) One selected by the Iowa medical society.

(3) One selected by the American college of cardiology, Iowa chapter.

b. Two licensed pharmacists selected by the Iowa pharmacy association.

c. Two laypersons selected by the commissioner.

EXPLANATION

This bill creates new Code section 514C.14 which provides that a policy or contract providing for third-party payment or prepayment of health care or medical expenses shall not exclude coverage for a prescription drug for a particular use on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the United States food and drug administration, if the drug is approved for use by the United States food and drug administration; the drug is prescribed by a licensed health care provider, participating under the policy or contract, for appropriate medical treatment; and the

drug has been recognized for the medical treatment for which it was prescribed by the American hospital formulary service drug information, the United States pharmacopoeia dispensing information, drugdex, or one article from a major peer-reviewed medical journal that presents data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal. The bill provides that such coverage also includes medically necessary services associated with the administration of the drug.

The bill applies to third-party payment provider contracts or policies delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2000.

MAR 18 1999

COMMERCE AND REGULATION

HOUSE FILE 726

BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HSB 243)

Passed House, Date _____ Passed Senate, Date _____

Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____

Approved _____

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S.F. _____ H.F. 726

Section 1. LEGISLATIVE FINDINGS. The Iowa general assembly finds and declares all of the following:

1. Third-party payors have denied payment for prescription drugs that have been approved by the United States food and drug administration, when the drugs are prescribed for uses other than those stated on the marketing label approved by the United States food and drug administration, while other insurers with similar coverage terms do pay for off-label use. Denial of payment for off-label uses interrupts necessary and appropriate treatment for persons being treated for life-threatening illnesses by competent, responsible medical professionals.

2. The United States food and drug administration and the United States department of health and human services recognize the wide variety of effective uses of federally approved drugs through off-label uses. Continuing medical research has demonstrated effective, new uses of federally approved drugs. Information on the appropriate off-label use of federally approved drugs is obtained from compendia published by the United States pharmacopeial convention or the American society of hospital pharmacists. In addition, scientific studies of off-label use of drugs published in recognized peer-reviewed professional journals provide information on appropriate off-label uses of drugs. The federal Omnibus Budget Reconciliation Act of 1990 recognizes these compendia and peer-reviewed literature as appropriate sources for reimbursement.

3. The federal approval process for drugs is very expensive and time-consuming. Use of federally approved drugs for off-label uses provides efficacious drugs at a lower cost. To require that all appropriate uses of a drug undergo approval by the United States food and drug administration would substantially increase the cost of drugs, and delay or deny patients' ability to obtain medically effective treatment. To require approval for all new uses would add to

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

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b. "Standard reference compendia" means any of the following:

(1) The United States pharmacopoeia drug information.

(2) The American hospital formulary service drug information.

(3) Drugdex.

2. Notwithstanding section 514C.6, a policy or contract providing for third-party payment or prepayment of health care or medical expenses shall not exclude coverage for a prescription drug for a particular use on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the United States food and drug administration, provided that all the following conditions have been met:

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

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

c. The drug has been recognized for the medical treatment for which it was prescribed by one of the following:

(1) The American hospital formulary service drug information.

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(3) One article from a major peer-reviewed medical journal that presents data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

3. A participating health care provider, if requested by a third-party payor, shall submit to the third-party payor documentation as identified in subsection 2, paragraph "c".

4. Coverage for a drug pursuant to this section also includes medically necessary services associated with the administration of the drug.

5. This section applies to the following classes of third-party payment provider contracts or policies delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2000:

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

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

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

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

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

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

6. a. This section shall not be construed to alter existing laws with regard to provisions limiting the coverage of drugs that have not been approved by the United States food and drug administration.

b. This section shall not be construed to require coverage for experimental drugs not otherwise approved for any use by the United States food and drug administration.

c. This section shall not reduce or limit coverage for off-label use of drugs otherwise required by law or contract.

7. The commissioner shall create a panel of seven experts to review off-label uses not included in any of the three standard reference compendia or in the medical literature and to give advice to the commissioner in such instances as to whether a particular off-label use is medically appropriate. The panel shall make such recommendations from time to time and whenever a dispute about payment for an off-label use is brought to the commissioner. The seven-member panel shall include all of the following:

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c. One layperson selected by the commissioner.

EXPLANATION

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drug has been recognized for the medical treatment for which it was prescribed by the American hospital formulary service drug information, the United States pharmacopoeia dispensing information, drugdex, or one article from a major peer-reviewed medical journal that presents data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal. The bill provides that such coverage also includes medically necessary services associated with the administration of the drug.

The bill applies to third-party payment provider contracts or policies delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2000.