

**As Reported by the House Insurance Committee**

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**H. B. No. 384**

**Representative Bolon**

**Cosponsors: Representatives Balderson, Boyd, Chandler, Daniels,  
Derickson, Dolan, Domenick, Evans, Fende, Garland, Hackett, Hagan, Harris,  
Harwood, Heard, Letson, Lundy, Newcomb, Pillich, Sears, Ujvagi,  
Weddington**

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**A B I L L**

To amend sections 1751.66 and 3923.60 of the Revised 1  
Code to use the compendia adopted by the United 2  
States Department of Health and Human Services to 3  
determine whether an insurer may exclude coverage 4  
for off-label drug usage. 5

**BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:**

**Section 1.** That sections 1751.66 and 3923.60 of the Revised 6  
Code be amended to read as follows: 7

**Sec. 1751.66.** (A) No individual or group health insuring 8  
corporation policy, contract, or agreement that provides coverage 9  
for prescription drugs shall limit or exclude coverage for any 10  
drug approved by the United States food and drug administration on 11  
the basis that the drug has not been approved by the United States 12  
food and drug administration for the treatment of the particular 13  
indication for which the drug has been prescribed, provided the 14  
drug has been recognized as safe and effective for treatment of 15  
that indication in one or more of the standard medical reference 16

~~compendia specified in division (B)(1) of this section adopted by~~ 17  
~~the United States department of health and human services under 42~~ 18  
~~U.S.C. 1395x (t)(2), as amended,~~ or in medical literature that 19  
meets the criteria specified in division (B)(2) of this section. 20

~~(B)(1) The compendia accepted for purposes of division (A) of~~ 21  
~~this section are the following:~~ 22

~~(a) The "AMA drug evaluations," a publication of the American~~ 23  
~~medical association;~~ 24

~~(b) The "AHFS (American hospital formulary service) drug~~ 25  
~~information," a publication of the American society of health~~ 26  
~~system pharmacists;~~ 27

~~(c) "Drug information for the health care provider," a~~ 28  
~~publication of the United States pharmacopoeia convention.~~ 29

~~(2) Medical literature may be accepted for purposes of~~ 30  
division (A) of this section only if all of the following apply: 31

~~(a)(1) Two articles from major peer-reviewed professional~~ 32  
medical journals have recognized, based on scientific or medical 33  
criteria, the drug's safety and effectiveness for treatment of the 34  
indication for which it has been prescribed; 35

~~(b)(2) No article from a major peer-reviewed professional~~ 36  
medical journal has concluded, based on scientific or medical 37  
criteria, that the drug is unsafe or ineffective or that the 38  
drug's safety and effectiveness cannot be determined for the 39  
treatment of the indication for which it has been prescribed; 40

~~(c)(3) Each article meets the uniform requirements for~~ 41  
manuscripts submitted to biomedical journals established by the 42  
international committee of medical journal editors or is published 43  
in a journal specified by the United States department of health 44  
and human services pursuant to Section 1861(t)(2)(B) of the 45  
"Social Security Act," 107 Stat. 591 (1993), 42 U.S.C. 1395 46

(x)(t)(2)(B), as amended, as accepted peer-reviewed medical literature. 47  
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(C) Coverage of a drug required by division (A) of this section includes medically necessary services associated with the administration of the drug. 49  
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(D) Division (A) of this section shall not be construed to do any of the following: 52  
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(1) Require coverage for any drug if the United States food and drug administration has determined its use to be contraindicated for the treatment of the particular indication for which the drug has been prescribed; 54  
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(2) Require coverage for experimental drugs not approved for any indication by the United States food and drug administration; 58  
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(3) Alter any law with regard to provisions limiting the coverage of drugs that have not been approved by the United States food and drug administration; 60  
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(4) Require reimbursement or coverage for any drug not included in the drug formulary or list of covered drugs specified in a health insuring corporation contract; 63  
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(5) Prohibit a health insuring corporation from limiting or excluding coverage of a drug, provided that the decision to limit or exclude coverage of the drug is not based primarily on the coverage of drugs required by this section. 66  
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(E) This section applies only to health insuring corporation policies, contracts, and agreements that are described in division (A) of this section and that are delivered, issued for delivery, or renewed in this state on or after July 1, 1997. 70  
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**Sec. 3923.60.** (A) Notwithstanding section 3901.71 of the Revised Code, no group or individual policy of sickness and accident insurance that provides coverage for prescription drugs 74  
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shall limit or exclude coverage for any drug approved by the 77  
United States food and drug administration on the basis that the 78  
drug has not been approved by the United States food and drug 79  
administration for the treatment of the particular indication for 80  
which the drug has been prescribed, provided the drug has been 81  
recognized as safe and effective for treatment of that indication 82  
in one or more of the standard medical reference compendia 83  
~~specified in division (B)(1) of this section~~ adopted by the United 84  
States department of health and human services under 42 U.S.C. 85  
1395x (t)(2), as amended, or in medical literature that meets the 86  
criteria specified in division (B)(2) of this section. 87

~~(B)(1) The compendia accepted for purposes of division (A) of~~ 88  
~~this section are the following:~~ 89

~~(a) The "AMA drug evaluations," a publication of the American~~ 90  
~~medical association;~~ 91

~~(b) The "AHFS (American hospital formulary service) drug~~ 92  
~~information," a publication of the American society of health~~ 93  
~~system pharmacists;~~ 94

~~(c) "Drug information for the health care provider," a~~ 95  
~~publication of the United States pharmacopeia convention.~~ 96

~~(2)~~ Medical literature may be accepted for purposes of 97  
division (A) of this section only if all of the following apply: 98

~~(a)(1)~~ Two articles from major peer-reviewed professional 99  
medical journals have recognized, based on scientific or medical 100  
criteria, the drug's safety and effectiveness for treatment of the 101  
indication for which it has been prescribed; 102

~~(b)(2)~~ No article from a major peer-reviewed professional 103  
medical journal has concluded, based on scientific or medical 104  
criteria, that the drug is unsafe or ineffective or that the 105  
drug's safety and effectiveness cannot be determined for the 106  
treatment of the indication for which it has been prescribed; 107

~~(e)~~(3) Each article meets the uniform requirements for 108  
manuscripts submitted to biomedical journals established by the 109  
international committee of medical journal editors or is published 110  
in a journal specified by the United States department of health 111  
and human services pursuant to section 1861(t)(2)(B) of the 112  
"Social Security Act," 107 Stat. 591 (1993), 42 U.S.C. 113  
1395x(t)(2)(B), as amended, as acceptable peer-reviewed medical 114  
literature. 115

(C) Coverage of a drug required by division (A) of this 116  
section includes medically necessary services associated with the 117  
administration of the drug. 118

(D) Division (A) of this section shall not be construed to do 119  
any of the following: 120

(1) Require coverage for any drug if the United States food 121  
and drug administration has determined its use to be 122  
contraindicated for the treatment of the particular indication for 123  
which the drug has been prescribed; 124

(2) Require coverage for experimental drugs not approved for 125  
any indication by the United States food and drug administration; 126

(3) Alter any law with regard to provisions limiting the 127  
coverage of drugs that have not been approved by the United States 128  
food and drug administration; 129

(4) Require reimbursement or coverage for any drug not 130  
included in the drug formulary or list of covered drugs specified 131  
in a policy of sickness and accident insurance; 132

(5) Prohibit a policy of sickness and accident insurance from 133  
limiting or excluding coverage of a drug, provided that the 134  
decision to limit or exclude coverage of the drug is not based 135  
primarily on the coverage of drugs required by this section. 136

(E) This section, as amended, applies only to policies of 137

sickness and accident insurance that are described in division (A) 138  
of this section and that are delivered, issued for delivery, or 139  
renewed in this state on or after the effective date of this 140  
amendment. 141

**Section 2.** That existing sections 1751.66 and 3923.60 of the 142  
Revised Code are hereby repealed. 143