As Passed by the House

128th General Assembly
Regular Session **H. B. No. 384**
2009-2010

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, Batchelder, Belcher, Blair, Book, Boose, Brown, Burke, Carney, Celeste, Coley, Combs, DeBose, DeGeeter, Driehaus, Dyer, Foley, Gardner, Garrison, Gerberry, Goyal, Grossman, Hall, Hite, Hottinger, Lehner, Luckie, Mandel, Mecklenborg, Okey, Otterman, Patten, Phillips, Pryor, Reece, Sayre, Skindell, Slesnick, Snitchler, Stewart, Uecker, Wachtmann, Williams, B., Winburn, Yuko, Zehringer

A B I L L

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

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

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

Sec. 1751.66. (A) No individual or group health insuring corporation policy, contract, or agreement that provides coverage for prescription drugs shall limit or exclude coverage for any drug approved by the United States food and drug administration on

the basis that the drug has not been approved by the United States food and drug administration for the treatment of the particular indication for which the drug has been prescribed, provided the drug has been recognized as safe and effective for treatment of that indication in one or more of the standard medical reference compendia ~~specified in division (B)(1) of this section~~ adopted by the United States department of health and human services under 42 U.S.C. 1395x (t)(2), as amended, or in medical literature that meets the criteria specified in division (B)~~(2)~~ of this section.

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

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

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

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

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

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

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

~~(c)~~(3) Each article meets the uniform requirements for

manuscripts submitted to biomedical journals established by the international committee of medical journal editors or is published in a journal specified by the United States department of health and human services pursuant to Section 1861(t)(2)(B) of the "Social Security Act," 107 Stat. 591 (1993), 42 U.S.C. 1395 (x)(t)(2)(B), as amended, as accepted peer-reviewed medical literature.

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

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

(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;

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

(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;

(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;

(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.

(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.

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 shall limit or exclude coverage for any drug approved by the United States food and drug administration on the basis that the drug has not been approved by the United States food and drug administration for the treatment of the particular indication for which the drug has been prescribed, provided the drug has been recognized as safe and effective for treatment of that indication in one or more of the standard medical reference compendia ~~specified in division (B)(1) of this section~~ adopted by the United States department of health and human services under 42 U.S.C. 1395x (t)(2), as amended, or in medical literature that meets the criteria specified in division (B)~~(2)~~ of this section.

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

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

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

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

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

~~(a)~~(1) Two articles from major peer-reviewed professional medical journals have recognized, based on scientific or medical criteria, the drug's safety and effectiveness for treatment of the

indication for which it has been prescribed;

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

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

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

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

(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;

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

(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;

(4) Require reimbursement or coverage for any drug not included in the drug formulary or list of covered drugs specified

in a policy of sickness and accident insurance;

(5) Prohibit a policy of sickness and accident insurance 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.

(E) This section, as amended, applies only to policies of sickness and accident insurance that are described in division (A) of this section and that are delivered, issued for delivery, or renewed in this state on or after the effective date of this amendment.

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