Ohio Legislative Service Commission

Bill Analysis

Katie Bentley

H.B. 384

128th General Assembly
(As Introduced)

Reps. Bolon, Balderson, Boyd, Chandler, Daniels, Derickson, Dolan, Domenick, Evans, Fende, Garland, Hackett, Hagan, Harris, Harwood, Heard, Letson, Lundy, Newcomb, Pillich, Sears, Ujvagi, Weddington

BILL SUMMARY

- Replaces, for purposes of insurance coverage of off-label drug use, the compendia used to determine if a drug is safe and effective for treatment of an indication with the standard medical reference compendia adopted by the United States Department of Health and Human Services under the federal law.

CONTENT AND OPERATION

Current law

Current law prohibits health insuring corporation and sickness and accident insurance policies, contracts, and agreements that provide coverage for prescription drugs from limiting or excluding 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. The prohibition applies if the drug has been recognized as safe and effective for treatment of the indication in one or more of the following standard medical reference compendia:

(1) The "AMA drug evaluations," a publication of the American Medical Association;

(2) The "AHFS (American Hospital Formulary Service) Drug Information," a publication of the American Society of Health System Pharmacists;

(3) "Drug Information for the Health Care Provider," a publication of the United States Pharmacopoeia Convention.

The prohibition also applies if the drug has been recognized as safe and effective for treatment of the indication in medical literature that meets the criteria specified in statute. (R.C. 1751.66 and 3923.60.)

Operation of the bill

The bill replaces the standard medical reference compendia listed above with the standard medical reference compendia adopted by the United States Department of Health and Human Services under the federal law (R.C. 1751.66 and 3923.60). Under federal law, the term "medically accepted indication," with respect to the use of a drug, includes any use that has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if the drug has been approved by the Food and Drug Administration and either of the following are true:

(1) The use of the drug is supported by one or more citations that are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia;

(2) The carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in the above publications.

Under federal law, the Secretary of Health and Human Services may revise the above list of compendia as is appropriate for identifying medically accepted indications for drugs. However, the Secretary may not include any compendia unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests. (42 U.S.C. 1395x(t)(2).)

HISTORY

ACTION	DATE
Introduced	12-01-09

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