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114TH CONGRESS
1ST SESSION

H. R. 2452

To amend the Federal Food, Drug, and Cosmetic Act with respect to facilitating dissemination of health care economic information.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. LONG (for himself, Mr. SCHRADER, and Mr. BURGESS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to facilitating dissemination of health care economic information.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. FACILITATING DISSEMINATION OF HEALTH CARE ECONOMIC INFORMATION.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)) is amended—

(1) by striking ''(a) If its'' and inserting ''(a)(1) If its'';

(2) by striking ''a formulary committee, or other similar entity, in the course of the committee

or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations'' and inserting ''a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement'';

(3) by striking ''directly relates'' and inserting ''relates'';

(4) by striking ''and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph'' and inserting '', is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act shall not apply to health care economic information pro-

vided to such a payor, committee, or entity in accordance with this paragraph''; and

(5) by striking ''In this paragraph, the term'' and all that follows and inserting the following:

''(2)(A) For purposes of this paragraph, the term 'health care economic information' means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analyses may be comparative to the use of another drug, to another health care intervention, or to no intervention.

''(B) Such term does not include any analysis that relates only to an indication that is not approved under section 505 or under section 351 of the Public Health Service Act for such drug.''.

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