AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 2026 OFFERED BY MR. GUTHRIE OF KENTUCKY

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Information Exchange Act of 2018''.

SEC. 2. FACILITATING EXCHANGE OF INFORMATION PRIOR TO APPROVAL.

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

(1) in paragraph (1)—

(A) by striking ''formulary committee'' and inserting ''formulary or technology review committee'';

(B) by striking ''drugs for coverage'' and inserting ''drugs or devices for coverage'';

(C) by striking ''approved under section 505 or under section 351(a) of the Public Health Service Act for such drug'' and inserting ''approved, granted marketing authorization, cleared, or licensed pursuant to section

505, 510(k), 513(f), or 515 of this Act or pursuant to section 351 of the Public Health Service Act for such drug or device'';

(D) by striking ''approved for the drug under section 505 or under section 351 of the Public Health Service Act'' and inserting ''of the drug or device approved, granted marketing authorization, cleared, or licensed pursuant to section 505, 510(k), 513(f), or 515 of this Act or pursuant to section 351 of the Public Health Service Act''; and

(E) by striking ''The requirements set forth in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act'' and inserting ''The requirements set forth in section 505(a), 510(k), 513(f), or 515 of this Act or section 351 of the Public Health Service Act'';

(2) by redesignating subparagraph (2) as subparagraph (3);

(3) by inserting after subparagraph (1) the following:

''(2)(A) Health care economic information or scientific information provided to a payor, formulary or technology review 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 or devices for coverage, reimbursement, or other population-based health care management, shall not be considered false or misleading or any other form of misbranding under this section, or a violation of section 505, 510(k), 513(f), or 515 of this Act or section 351 of the Public Health Service Act, if it is truthful, nonmisleading, and based on competent and reliable scientific evidence and relates to an investigational product or investigational use of a drug or device.

''(B) In order for information relating to an investigational use of an approved, cleared, or licensed drug or device to be provided pursuant to this subparagraph—

''(i) the study or studies the sponsor could objectively anticipate to be sufficient to support the approval, clearance, or licensing of such use must have been conducted;

''(ii) the information must be derived from such study or studies;

''(iii) the sponsor must intend that a submission will be made to the Secretary for approval, marketing authorization, clearance, or licensing of the use, if required; and

''(iv) the information must include, where applicable, a conspicuous and prominent statement describing any material differences between the information provided and the labeling of the drug or device approved, granted marketing authorization, cleared, or licensed pursuant to section 505, 510(k), 513(f), or 515 of this Act or pursuant to section 351 of the Public Health Service Act.

''(C) For purposes of this subparagraph, scientific information includes clinical and pre-clinical data and results relating to a product or use that has not been approved, granted marketing authorization, cleared, or licensed and is being investigated or developed.'';

(4) in subparagraph (3), as redesignated—

(A) by striking ''(A)'';

(B) by striking clause (B); and

(C) by striking ''drug'' each place it appears and inserting ''drug or device''; and

(5) by adding at the end the following:

''(4) Nothing in this paragraph shall be construed to limit the ability of manufacturers or sponsors of drugs or devices to engage in communications or activities not specified in subparagraph (2) or (3) that are otherwise permissible.''.

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