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116TH CONGRESS
1ST SESSION

H. R. 4400

To amend the Public Health Service Act to provide for an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 2019

Mr. BUCSHON (for himself and Mr. ENGEL) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Public Health Service Act to provide for an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Advancing Education on Biosimilars Act of 2019''.

SEC. 2. EDUCATION ON BIOLOGICAL PRODUCTS.

(a) WEBSITE; CONTINUING EDUCATION.—Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following:

"SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.

"(a) INTERNET WEBSITE.—

"(1) IN GENERAL.—The Secretary shall maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

"(2) CONTENT.—Educational materials provided under paragraph (1) may include—

"(A) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;

"(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clin-

ical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

''(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

''(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), including the standards for review and licensing of each such type of biological product.

''(3) FORMAT.—The educational materials provided under paragraph (1) may be—

''(A) in formats such as webinars, continuing medical education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

''(B) tailored for the unique needs of health care providers, patients, caregivers, and

other audiences, as the Secretary determines appropriate.

''(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish the following information:

''(A) The action package of each biological product licensed under subsection (a) or (k).

''(B) The summary review of each biological product licensed under subsection (a) or (k).

''(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

''(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.''.

(b) APPLICATION UNDER THE MEDICARE MERIT-BASED INCENTIVE PAYMENT SYSTEM.—Section 1848(q)(5)(C) of the Social Security Act (42 U.S.C. 1395w–4(q)(5)(C)) is amended by adding at the end the following new clause:

"(iv) CLINICAL MEDICAL EDUCATION PROGRAM ON BIOSIMILAR BIOLOGICAL PRODUCTS.—Completion of a clinical medical education program developed or improved under section 352A(b) of the Public Health Service Act by a MIPS eligible professional during a performance period shall earn such eligible professional one-half of the highest potential score for the performance category described in paragraph (2)(A)(iii) for such performance period. A MIPS eligible professional may only count the completion of such a program for purposes of such category one time during the eligible professional's lifetime.".

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