II

116TH CONGRESS
1ST SESSION

S. 1681

To educate health care providers and the public on biosimilar biological products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 23 (legislative day, MAY 22), 2019

Mr. ENZI (for himself and Ms. HASSAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To educate health care providers and the public on biosimilar 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) IN GENERAL.—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 establish, maintain, and operate an internet website consisting of educational materials regarding the meaning and use of biosimilar biological products and interchangeable biological products.

''(2) FORMAT.—The educational materials provided under paragraph (1)—

''(A) may be in the form of webinars, continuing medical education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats, as the Secretary determines appropriate;

''(B) shall be presented in a manner, using simple terminology, that is easily comprehended by appropriate target audiences, including accounting, to the extent practicable, for varying levels of health literacy among patients and caregivers;

''(C) shall be tailored for the unique needs of appropriate target audiences, including—

''(i) health care providers with prescribing authority or dispensing authority under applicable State law, including physicians, nurses, nurse practitioners, physi-

cian assistants, pharmacists, and pharmacy technicians; and

''(ii) patients and caregivers; and

''(D) may, as appropriate, be additionally tailored to health care providers practicing in specialties in which biological products commonly are prescribed or to patient populations to whom biological products commonly are prescribed or administered.

''(3) CONTENT.—Educational materials provided under paragraph (1) shall include explanations of—

''(A) key statutory and regulatory definitions, including the definitions of the terms 'biosimilar' and 'interchangeable', and clarification that an interchangeable product is not superior in quality to a biosimilar biological product;

''(B) how the Secretary determines the safety, purity, and potency of biological products that are the subjects of applications under subsections (a) and (k) of section 351;

''(C) the application of the same quality and manufacturing standards for biological products under 351(a), biosimilar biological

products under 351(k), and interchangeable biological products under 351(k)(4);

''(D) the development program and totality of the evidence required for biosimilar biological product development and how prescribers can evaluate such information;

''(E) the process for reporting adverse events for all biological products, including biosimilar and interchangeable biological products;

''(F) the relationship between—

''(i) variation among biological products licensed under section 351(k) and their reference products licensed under section 351(a); and

''(ii) lot-to-lot variability for a biological product licensed under section 351(a) or section 351(k) (including interchangeable biological products);

''(G) how the Food and Drug Administration assesses data regarding the risk of immunogenicity for originator biological products licensed under section 351(a) and biosimilar biological products licensed under section 351(k);

''(H) whether the role of analytical characterization is novel to biosimilar biological product development; and

''(I) how the Food and Drug Administration considers biosimilar biological products to be as safe and effective as their reference products.

''(4) OTHER INFORMATION.—In addition to the information described in paragraph (3), the internet website established under paragraph (1) shall include the following information (with redactions as required by law for trade secret and confidential commercial information), as a single, searchable database:

''(A) The action package of each biological product licensed under subsection (a) or (k), within 30 days of approval of the application, or, in the case of a biological product licensed before the date of enactment of the Advancing Education on Biosimilars Act of 2019, not later than 1 year after such date of enactment.

''(B) The summary review of each biological product licensed under subsection (a) or (k), within 48 hours of approval of the application, or, in the case of a biological product licensed

before the date of enactment of the Advancing Education on Biosimilars Act of 2019, not later than 1 year after such date of enactment.

"(C) The history and timing of manufacturing changes with respect to biological products licensed under section 351(a).

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

fessional 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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