II

118TH CONGRESS
1ST SESSION

S. 2916

To provide for digital communication of prescribing information for drugs (including biological products), and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 26 (legislative day, SEPTEMBER 22), 2023

Mr. BOOKER (for himself and Mr. MULLIN) 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 provide for digital communication of prescribing information for drugs (including 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 ''Prescription Information Modernization Act of 2023''.

SEC. 2. DIGITAL COMMUNICATION OF FDA-APPROVED PRESCRIBING INFORMATION FOR DRUGS (INCLUDING BIOLOGICAL PRODUCTS).

(a) IN GENERAL.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is amended by adding at the end the following: ''Required prescribing information for drugs subject to section 503(b)(1) may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, that the manufacturer affords prescribers and dispensers the opportunity to elect to also continue to receive all such information in paper form or to request paper labeling on an as-needed basis, and, after such request, that the manufacturer promptly provides the requested information without additional cost.''.

(b) RULEMAKING.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue final regulations to—

(A) implement the amendment made by subsection (a); and

(B) provide instructions on how health care professionals can receive paper copies of prescribing information directly from the manufacturer or distributor if desired.

(2) ECONOMIC IMPACTS.—The Secretary of Health and Human Services shall design the regulations required by paragraph (1) so as to minimize the adverse economic impacts of such regulations on prescribers and dispensers.

(c) PUBLIC WORKSHOP.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall hold a public workshop with relevant stakeholders to discuss how to continue to optimize the format, accessibility, and usability of prescribing information.

(d) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to drugs introduced or delivered for introduction into interstate commerce on or after the sooner of—

(1) the date that is 2 years after the date of the enactment of this Act; or

(2) the effective date of the final regulations promulgated to implement such amendment.

(e) DEFINITION.—In this section, the term ''drug'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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