

118TH CONGRESS  
1ST SESSION

# H. R. 1503

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

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2023

Mrs. HARSHBARGER (for herself and Ms. SHERRILL) introduced the following  
bill; which was referred to the Committee on Energy and Commerce

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## A BILL

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

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Prescription Informa-  
5 tion Modernization Act of 2023”.

6 **SEC. 2. DIGITAL COMMUNICATION OF FDA-APPROVED PRE-**  
7 **SCRIBING INFORMATION FOR DRUGS (IN-**  
8 **CLUDING BIOLOGICAL PRODUCTS).**

9 (a) IN GENERAL.—Section 502(f) of the Federal  
10 Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is

1 amended by adding at the end the following: “Required  
2 prescribing information for drugs subject to section  
3 503(b)(1) may be made available solely by electronic  
4 means provided that the labeling complies with all applica-  
5 ble requirements of law, that the manufacturer affords  
6 prescribers and dispensers the opportunity to elect to also  
7 continue to receive all such information in paper form, or  
8 to request paper labeling on an as-needed basis, and after  
9 such request, and that the manufacturer promptly pro-  
10 vides the requested information without additional cost.”.

11 (b) RULEMAKING.—

12 (1) IN GENERAL.—Not later than 1 year after  
13 the date of the enactment of this Act, the Secretary  
14 of Health and Human Services shall issue final reg-  
15 ulations to—

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

18 (B) provide instructions on how health  
19 care professionals can receive paper copies of  
20 prescribing information directly from the manu-  
21 facturer or distributor if desired.

22 (2) ECONOMIC IMPACTS.—The Secretary of  
23 Health and Human Services shall design the regula-  
24 tions required by paragraph (1) so as to minimize

1 the adverse economic impacts of such regulations on  
2 prescribers and dispensers.

3 (c) PUBLIC WORKSHOP.—Not later than 2 years  
4 after the date of the enactment of this Act, the Secretary  
5 of Health and Human Services, acting through the Com-  
6 missioner of Food and Drugs, shall hold a public workshop  
7 with relevant stakeholders to discuss how to continue to  
8 optimize the format, accessibility, and usability of pre-  
9 scribing information.

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

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

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

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

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