



(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mrs. HARSHBARGER introduced the following bill; which was referred to the
Committee on _____

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 2025”.

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

4 (a) IN GENERAL.—Section 502(f) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is
6 amended by adding at the end the following: “Required
7 prescribing information for drugs subject to section
8 503(b)(1) may be made available solely by electronic
9 means provided that the labeling complies with all applica-
10 ble requirements of law, that the manufacturer affords
11 prescribers and dispensers the opportunity to elect to also
12 continue to receive all such information in paper form, or
13 to request paper labeling on an as-needed basis, and after
14 such request, and that the manufacturer promptly pro-
15 vides the requested information without additional cost.”.

16 (b) RULEMAKING.—

17 (1) IN GENERAL.—Not later than 1 year after
18 the date of the enactment of this Act, the Secretary
19 of Health and Human Services shall issue final reg-
20 ulations to—

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

23 (B) provide instructions on how health
24 care professionals can receive paper copies of
25 prescribing information directly from the manu-
26 facturer or distributor if desired.

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

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

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

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

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

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