

117TH CONGRESS
2D SESSION

S. _____

To preserve access to abortion medications.

IN THE SENATE OF THE UNITED STATES

Ms. SMITH introduced the following bill; which was read twice and referred
to the Committee on _____

A BILL

To preserve access to abortion medications.

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 “Protecting Access to
5 Medication Abortion Act”.

6 **SEC. 2. MODIFICATION OF REMS.**

7 (a) IN GENERAL.—The Secretary of Health and
8 Human Services (referred to in this section as the “Sec-
9 retary”) shall require the responsible person involved to
10 submit a proposal under subsection (g)(4)(A) of section
11 505–1 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 355–1) to modify the risk evaluation and mitiga-

1 tion strategy under such section that applies to
2 mifepristone so that—

3 (1) the in-person dispensing requirement is re-
4 moved from such risk evaluation and mitigation
5 strategy;

6 (2) patients may access prescriptions for such
7 drug via telehealth; and

8 (3) all pharmacies that are certified to dispense
9 such drug are permitted to, at minimum, dispense
10 and mail such drug to patients.

11 (b) MODIFICATIONS.—Nothing in subsection (a) shall
12 be construed to prevent the Secretary from approving a
13 modification to the risk evaluation and mitigation strategy
14 for mifepristone based on sound scientific evidence and in
15 accordance with section 505–1(h) of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 355–1(h)). Any modi-
17 fications to such risk evaluation and mitigation strategy
18 made after the proposal to modify required pursuant to
19 subsection (a) shall be in accordance with the require-
20 ments under paragraphs (1), (2), and (3) of such sub-
21 section, unless the Secretary, based on sound scientific evi-
22 dence and in accordance with section 505–1 of such Act
23 (21 U.S.C. 355–1), determines that a risk evaluation and
24 mitigation strategy for mifepristone is no longer nec-
25 essary.

1 (c) CLARIFICATION.—Nothing in subsection (a) shall
2 be construed to limit the authority of the Secretary to im-
3 pose the requirements described in paragraphs (1), (2),
4 and (3) of such subsection to a risk evaluation and mitiga-
5 tion strategy under section 505–1 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 355–1) for any drug
7 other than mifepristone.

8 (d) DEFINITION.—In this section, the term
9 “mifepristone” means mifepristone that is—

10 (1) approved under subsection (c) or (j) of sec-
11 tion 505 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 355);

13 (2) indicated for medical abortion; and

14 (3) subject to a risk evaluation and mitigation
15 strategy under section 505–1 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 355–1).