

119TH CONGRESS
1ST SESSION

S. 3346

To establish a special registration under the Controlled Substances Act for schedule I eligible investigational drugs under the Federal Right to Try law.

IN THE SENATE OF THE UNITED STATES

DECEMBER 4, 2025

Mr. BOOKER (for himself and Mr. PAUL) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To establish a special registration under the Controlled Substances Act for schedule I eligible investigational drugs under the Federal Right to Try law.

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 “Freedom to Heal Act
5 of 2025”.

1 **SEC. 2. SPECIAL REGISTRATION REQUIREMENTS RELATED**
 2 **TO RIGHT TO TRY.**

3 Section 303 of the Controlled Substances Act (21
 4 U.S.C. 823) is amended by adding at the end the fol-
 5 lowing:

6 “(p) SPECIAL REGISTRATION FOR SCHEDULE I ELI-
 7 GIBLE INVESTIGATIONAL DRUGS UNDER RIGHT TO
 8 TRY.—

9 “(1) DEFINITIONS.—In this subsection, the
 10 terms ‘eligible investigational drug’ and ‘eligible pa-
 11 tient’ have the meanings given those terms in section
 12 561B of the Federal Food, Drug, and Cosmetic Act
 13 (21 U.S.C. 360bbb–0a).

14 “(2) SPECIAL REGISTRATION PROCESS.—The
 15 Attorney General shall register physicians to directly
 16 administer eligible investigational drugs in schedule
 17 I to eligible patients under section 561B of the Fed-
 18 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 19 360bbb–0a) in accordance with paragraphs (3)
 20 through (8) of this subsection.

21 “(3) REQUIREMENTS.—

22 “(A) APPLICATION.—A physician desiring
 23 a registration to directly administer an eligible
 24 investigational drug as described in paragraph
 25 (2) shall submit to the Attorney General an ap-
 26 plication containing—

1 “(i) evidence of a valid registration to
2 dispense or administer controlled sub-
3 stances in schedules II through V;

4 “(ii) evidence of compliance with sec-
5 tion 561B of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 360bbb–0a), in-
7 cluding—

8 “(I) documentation from the
9 manufacturer or sponsor verifying the
10 investigational drug in schedule I is
11 an eligible investigational drug;

12 “(II) an agreement from the
13 manufacturer or sponsor to supply the
14 eligible investigational drug, along
15 with guidance on its administration,
16 to the requesting physician for the
17 treatment of eligible patients; and

18 “(III) an affirmation that the
19 physician will only directly administer
20 the eligible investigational drug to
21 treat eligible patients in a manner
22 consistent with the guidance provided
23 by the manufacturer or sponsor;

24 “(iii) the quantity of the eligible inves-
25 tigational drug to be supplied by the man-

1 ufacturer or sponsor to the physician to
2 treat eligible patients;

3 “(iv) evidence that the physician may
4 treat eligible patients with eligible inves-
5 tigational drugs under the laws of the
6 State in which the treatment will take
7 place;

8 “(v) evidence of training, credentials,
9 or experience relevant to treating patients
10 with the eligible investigational drug;

11 “(vi) a description of the site at which
12 the physician intends to store and admin-
13 ister the eligible investigational drug; and

14 “(vii) any additional information the
15 Attorney General determines necessary to
16 prevent diversion.

17 “(B) APPROVAL.—Not later than 45 days
18 after receiving an application containing the in-
19 formation required under subparagraph (A), the
20 Attorney General shall—

21 “(i) register the applicant; or

22 “(ii) serve an order to show cause
23 upon the applicant in accordance with sec-
24 tion 304(c).

1 “(4) ELECTRONIC SUBMISSIONS.—The Attorney
2 General shall provide a means for a physician to
3 submit an application under paragraph (3)(A) elec-
4 tronically.

5 “(5) LIMITATION ON AMOUNTS.—A physician
6 treating eligible patients with an eligible investiga-
7 tional drug in schedule I under this subsection may
8 only possess the amounts of the eligible investiga-
9 tional drug identified in—

10 “(A) the application submitted to the At-
11 torney General under paragraph (3)(A); or

12 “(B) a supplemental notification that the
13 physician may submit to the Attorney General
14 if the physician needs additional amounts of the
15 eligible investigational drug for the treatment of
16 eligible patients, which supplemental notifica-
17 tion—

18 “(i) shall include—

19 “(I) the name of the physician;

20 “(II) the additional quantity of
21 the eligible investigational drug need-
22 ed; and

23 “(III) an attestation that the
24 treatment with the eligible investiga-
25 tional drug is consistent with the

1 scope of treatment that was the sub-
2 ject of the application under para-
3 graph (3)(A); and

4 “(ii) shall be deemed approved on the
5 date that is 30 days after the date on
6 which the physician submits the supple-
7 mental notification to the Attorney Gen-
8 eral, unless the Attorney General serves an
9 order to show cause upon the applicant in
10 accordance with section 304(c).

11 “(6) SINGLE REGISTRATION FOR RELATED
12 TREATMENT SITES.—A physician may treat eligible
13 patients with an eligible investigational drug in
14 schedule I under a single registration under this
15 subsection if—

16 “(A) the treatment occurs exclusively on
17 sites all of which are—

18 “(i) within the same city or county;
19 and

20 “(ii) under the control of the same in-
21 stitution, organization, or agency; and

22 “(B) before commencing the treatment, the
23 physician notifies the Attorney General of each
24 site where the eligible investigational drug will

1 be stored or administered in accordance with
2 paragraph (3)(A)(vi).

3 “(7) RULEMAKING.—Notwithstanding the re-
4 quirements of section 553 of title 5, United States
5 Code, not later than 240 days after the date of en-
6 actment of this subsection, the Attorney General
7 shall issue an interim final rule to implement this
8 subsection, including with respect to—

9 “(A) the manner in which an eligible inves-
10 tigational drug may be delivered to an approved
11 registrant;

12 “(B) the storage and security of an eligible
13 investigational drug;

14 “(C) the maintenance of records for an ap-
15 proved registrant;

16 “(D) the process for renewal, suspension,
17 or revocation of a registration; and

18 “(E) any other matters necessary to en-
19 sure effective controls against diversion.

20 “(8) FINAL RULE.—Not later than 2 years
21 after issuing an interim final rule under paragraph
22 (7), the Attorney General shall issue a final rule to
23 implement this subsection in accordance with section
24 553 of title 5, United States Code.”.

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