

114TH CONGRESS
1ST SESSION

S. 483

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2015

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

A BILL

To improve enforcement efforts related to prescription drug diversion and abuse, 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 “Ensuring Patient Ac-
5 cess and Effective Drug Enforcement Act of 2015”.

6 **SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED**
7 **SUBSTANCES ACT.**

8 (a) DEFINITIONS.—

9 (1) FACTORS AS MAY BE RELEVANT TO AND
10 CONSISTENT WITH THE PUBLIC HEALTH AND SAFE-

1 TY.—Section 303 of the Controlled Substances Act
2 (21 U.S.C. 823) is amended by adding at the end
3 the following:

4 “(i) In this section, the phrase ‘factors as may be rel-
5 evant to and consistent with the public health and safety’
6 means factors that are relevant to and consistent with the
7 findings contained in section 101.”.

8 (2) IMMINENT DANGER TO THE PUBLIC
9 HEALTH OR SAFETY.—Section 304(d) of the Con-
10 trolled Substances Act (21 U.S.C. 824(d)) is amend-
11 ed—

12 (A) by striking “(d) The Attorney Gen-
13 eral” and inserting “(d)(1) The Attorney Gen-
14 eral”; and

15 (B) by adding at the end the following:

16 “(2) In this subsection, the phrase ‘imminent danger
17 to the public health or safety’ means that, in the absence
18 of an immediate suspension order, controlled substances
19 will continue to be distributed or dispensed by a registrant
20 who knows or should know through fulfilling the obliga-
21 tions of the registrant under this Act—

22 “(A) the dispensing is outside the usual course
23 of professional practice;

24 “(B) the distribution or dispensing poses a
25 present or foreseeable risk of adverse health con-

1 sequences or death due to the abuse or misuse of the
2 controlled substances; or

3 “(C) the controlled substances will continue to
4 be diverted outside of legitimate distribution chan-
5 nels.”.

6 (b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION
7 PLAN PRIOR TO REVOCATION OR SUSPENSION.—Sub-
8 section (c) of section 304 of the Controlled Substances Act
9 (21 U.S.C. 824) is amended—

10 (1) by striking the last two sentences;

11 (2) by striking “(c) Before” and inserting
12 “(c)(1) Before”; and

13 (3) by adding at the end the following:

14 “(2) An order to show cause under paragraph (1)
15 shall—

16 “(A) contain a statement of the basis for the
17 denial, revocation, or suspension, including specific
18 citations to any laws or regulations alleged to be vio-
19 lated by the applicant or registrant;

20 “(B) direct the applicant or registrant to ap-
21 pear before the Attorney General at a time and
22 place stated in the order, but not less than 30 days
23 after the date of receipt of the order; and

1 “(C) notify the applicant or registrant of the
2 opportunity to submit a corrective action plan on or
3 before the date of appearance.

4 “(3) Upon review of any corrective action plan sub-
5 mitted by an applicant or registrant pursuant to para-
6 graph (2), the Attorney General shall determine whether
7 denial, revocation or suspension proceedings should be dis-
8 continued, or deferred for the purposes of modification,
9 amendment, or clarification to such plan.

10 “(4) Proceedings to deny, revoke, or suspend shall
11 be conducted pursuant to this section in accordance with
12 subchapter II of chapter 5 of title 5, United States Code.
13 Such proceedings shall be independent of, and not in lieu
14 of, criminal prosecutions or other proceedings under this
15 title or any other law of the United States.

16 “(5) The requirements of this subsection shall not
17 apply to the issuance of an immediate suspension order
18 under subsection (d).”.

19 **SEC. 3. REPORT TO CONGRESS ON EFFECTS OF LAW EN-**
20 **FORCEMENT ACTIVITIES ON PATIENT AC-**
21 **CESS TO MEDICATIONS.**

22 (a) IN GENERAL.—Not later than 1 year after the
23 date of enactment of this Act, the Secretary of Health and
24 Human Services, acting through the Commissioner of
25 Food and Drugs and the Director of the Centers for Dis-

1 ease Control and Prevention, in coordination with the Ad-
2 ministrator of the Drug Enforcement Administration and
3 in consultation with the Secretary of Defense and the Sec-
4 retary of Veterans Affairs, shall submit a report to the
5 Committee on the Judiciary of the House of Representa-
6 tives, the Committee on Energy and Commerce of the
7 House of Representatives, the Committee on the Judiciary
8 of the Senate, and the Committee on Health, Education,
9 Labor, and Pensions of the Senate identifying—

10 (1) obstacles to legitimate patient access to con-
11 trolled substances;

12 (2) issues with diversion of controlled sub-
13 stances; and

14 (3) how collaboration between Federal, State,
15 local, and tribal law enforcement agencies and the
16 pharmaceutical industry can benefit patients and
17 prevent diversion and abuse of controlled substances.

18 (b) CONSULTATION.—The report under subsection
19 (a) shall incorporate feedback and recommendations from
20 the following:

21 (1) Patient groups.

22 (2) Pharmacies.

23 (3) Drug manufacturers.

24 (4) Common or contract carriers and ware-
25 housemen.

1 (5) Hospitals, physicians, and other health care
2 providers.

3 (6) State attorneys general.

4 (7) Federal, State, local, and tribal law enforce-
5 ment agencies.

6 (8) Health insurance providers and entities that
7 provide pharmacy benefit management services on
8 behalf of a health insurance provider.

9 (9) Wholesale drug distributors.

10 (10) Veterinarians.

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