

114TH CONGRESS
1ST SESSION

H. R. 471

IN THE SENATE OF THE UNITED STATES

APRIL 22, 2015

Received; read twice and referred to the Committee on the Judiciary

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Ensuring Patient Ac-
3 cess and Effective Drug Enforcement Act of 2015”.

4 **SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED**
5 **SUBSTANCES ACT.**

6 (a) DEFINITIONS.—

7 (1) FACTORS AS MAY BE RELEVANT TO AND
8 CONSISTENT WITH THE PUBLIC HEALTH AND SAFE-
9 TY.—Section 303 of the Controlled Substances Act
10 (21 U.S.C. 823) is amended by adding at the end
11 the following:

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

16 (2) IMMINENT DANGER TO THE PUBLIC
17 HEALTH OR SAFETY.—Section 304(d) of the Con-
18 trolled Substances Act (21 U.S.C. 824(d)) is amend-
19 ed—

20 (A) by striking “(d) The Attorney Gen-
21 eral” and inserting “(d)(1) The Attorney Gen-
22 eral”; and

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

24 “(2) In this subsection, the phrase ‘imminent danger
25 to the public health or safety’ means that, in the absence
26 of an immediate suspension order, controlled substances

1 will continue to be distributed or dispensed by a registrant
2 who knows or should know through fulfilling the obliga-
3 tions of the registrant under this Act—

4 “(A) the dispensing is outside the usual course
5 of professional practice;

6 “(B) the distribution or dispensing poses a
7 present or foreseeable risk of adverse health con-
8 sequences or death due to the abuse or misuse of the
9 controlled substances; or

10 “(C) the controlled substances will continue to
11 be diverted outside of legitimate distribution chan-
12 nels.”.

13 (b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION
14 PLAN PRIOR TO REVOCATION OR SUSPENSION.—Sub-
15 section (c) of section 304 of the Controlled Substances Act
16 (21 U.S.C. 824) is amended—

17 (1) by striking the last two sentences;

18 (2) by striking “(c) Before” and inserting
19 “(c)(1) Before”; and

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

21 “(2) An order to show cause under paragraph (1)
22 shall—

23 “(A) contain a statement of the basis for the
24 denial, revocation, or suspension, including specific

1 citations to any laws or regulations alleged to be vio-
2 lated by the applicant or registrant;

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

7 “(C) notify the applicant or registrant of the
8 opportunity to submit a corrective action plan on or
9 before the date of appearance.

10 “(3) Upon review of any corrective action plan sub-
11 mitted by an applicant or registrant pursuant to para-
12 graph (2), the Attorney General shall determine whether
13 denial, revocation or suspension proceedings should be dis-
14 continued, or deferred for the purposes of modification,
15 amendment, or clarification to such plan.

16 “(4) Proceedings to deny, revoke, or suspend shall
17 be conducted pursuant to this section in accordance with
18 subchapter II of chapter 5 of title 5, United States Code.
19 Such proceedings shall be independent of, and not in lieu
20 of, criminal prosecutions or other proceedings under this
21 title or any other law of the United States.

22 “(5) The requirements of this subsection shall not
23 apply to the issuance of an immediate suspension order
24 under subsection (d).”.

1 **SEC. 3. REPORT TO CONGRESS ON EFFECTS OF LAW EN-**
2 **FORCEMENT ACTIVITIES ON PATIENT AC-**
3 **CESS TO MEDICATIONS.**

4 (a) IN GENERAL.—Not later than 1 year after the
5 date of enactment of this Act, the Secretary of Health and
6 Human Services, acting through the Commissioner of
7 Food and Drugs and the Director of the Centers for Dis-
8 ease Control and Prevention, in coordination with the Ad-
9 ministrator of the Drug Enforcement Administration and
10 in consultation with the Secretary of Defense and the Sec-
11 retary of Veterans Affairs, shall submit a report to the
12 Committee on the Judiciary of the House of Representa-
13 tives, the Committee on Energy and Commerce of the
14 House of Representatives, the Committee on the Judiciary
15 of the Senate, and the Committee on Health, Education,
16 Labor, and Pensions of the Senate identifying—

17 (1) obstacles to legitimate patient access to con-
18 trolled substances;

19 (2) issues with diversion of controlled sub-
20 stances; and

21 (3) how collaboration between Federal, State,
22 local, and tribal law enforcement agencies and the
23 pharmaceutical industry can benefit patients and
24 prevent diversion and abuse of controlled substances.

1 (b) CONSULTATION.—The report under subsection
2 (a) shall incorporate feedback and recommendations from
3 the following:

4 (1) Patient groups.

5 (2) Pharmacies.

6 (3) Drug manufacturers.

7 (4) Common or contract carriers and ware-
8 housemen.

9 (5) Hospitals, physicians, and other health care
10 providers.

11 (6) State attorneys general.

12 (7) Federal, State, local, and tribal law enforce-
13 ment agencies.

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

17 (9) Wholesale drug distributors.

18 (10) Veterinarians.

Passed the House of Representatives April 21, 2015.

Attest:

KAREN L. HAAS,

Clerk.