

113TH CONGRESS
2^D SESSION

H. R. 4709

IN THE SENATE OF THE UNITED STATES

JULY 30, 2014

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

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 2014”.

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 “(A) will continue to be intentionally distrib-
2 uted or dispensed—

3 “(i) outside the usual course of profes-
4 sional practice; or

5 “(ii) in a manner that poses a present or
6 foreseeable risk of serious adverse health con-
7 sequences or death; or

8 “(B) will continue to be intentionally diverted
9 outside of legitimate distribution channels.”.

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

14 (1) by striking the last two sentences in such
15 subsection;

16 (2) by striking “(c) Before” and inserting
17 “(c)(1) Before”; and

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

19 “(2) An order to show cause under paragraph (1)
20 shall—

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

1 “(B) direct the applicant or registrant to ap-
2 pear before the Attorney General at a time and
3 place stated in the order, but no less than thirty
4 days after the date of receipt of the order; and

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

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

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

20 “(5) The requirements of this subsection shall not
21 apply to the issuance of an immediate suspension order
22 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 one 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, and in consultation with the
9 Administrator of the Drug Enforcement Administration
10 and the Director of National Drug Control Policy, shall
11 submit a report to the Committees on the Judiciary of
12 the House of Representatives, the Committee on Energy
13 and Commerce of the House of Representatives, the Com-
14 mittee on the Judiciary of the Senate, and the Committee
15 on Health, Education, Labor and Pensions of the Senate
16 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.

Passed the House of Representatives July 29, 2014.

Attest:

KAREN L. HAAS,

Clerk.