

Suspend the Rules and Pass the Bill, H.R. 4709, with An Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

113TH CONGRESS
2^D SESSION

H. R. 4709

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

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 2014

Mr. MARINO (for himself, Mrs. BLACKBURN, Mr. WELCH, and Ms. CHU) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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 2014”.

1 **SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED**
2 **SUBSTANCES ACT.**

3 (a) DEFINITIONS.—

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

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

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

17 (A) by striking “(d) The Attorney Gen-
18 eral” and inserting “(d)(1) The Attorney Gen-
19 eral”; and

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

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

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

1 “(i) outside the usual course of profes-
2 sional practice; or

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

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

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

12 (1) by striking the last two sentences in such
13 subsection;

14 (2) by striking “(c) Before” and inserting
15 “(c)(1) Before”; and

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

17 “(2) An order to show cause under paragraph (1)
18 shall—

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

23 “(B) direct the applicant or registrant to ap-
24 pear before the Attorney General at a time and

1 place stated in the order, but no less than thirty
2 days after the date of receipt of the order; and

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

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

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

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

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

24 (a) IN GENERAL.—Not later than one year after the
25 date of enactment of this Act, the Secretary of Health and

1 Human Services, acting through the Commissioner of
2 Food and Drugs and the Director of the Centers for Dis-
3 ease Control and Prevention, and in consultation with the
4 Administrator of the Drug Enforcement Administration
5 and the Director of National Drug Control Policy, shall
6 submit a report to the Committees on the Judiciary of
7 the House of Representatives, the Committee on Energy
8 and Commerce of the House of Representatives, the Com-
9 mittee on the Judiciary of the Senate, and the Committee
10 on Health, Education, Labor and Pensions of the Senate
11 identifying—

12 (1) obstacles to legitimate patient access to con-
13 trolled substances;

14 (2) issues with diversion of controlled sub-
15 stances; and

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

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

23 (1) Patient groups.

24 (2) Pharmacies.

25 (3) Drug manufacturers.

1 (4) Common or contract carriers and ware-
2 housemen.

3 (5) Hospitals, physicians, and other health care
4 providers.

5 (6) State attorneys general.

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

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

11 (9) Wholesale drug distributors.