

113TH CONGRESS
2D 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”.

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

8 (a) DEFINITIONS.—

1 (1) CONSISTENT WITH THE PUBLIC HEALTH
2 AND SAFETY.—Section 303 of the Controlled Sub-
3 stances Act (21 U.S.C. 823) is amended by adding
4 at the end the following:

5 “(j) In this section, the phrase ‘consistent with the
6 public health and safety’ means having a substantial rela-
7 tionship to this Act’s purpose of preventing diversion and
8 abuse of controlled substances.”.

9 (2) IMMINENT DANGER.—Section 304(d) of the
10 Controlled Substances Act (21 U.S.C. 824(d)) is
11 amended—

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 term ‘imminent danger’
17 means a significant and present risk of death or serious
18 bodily harm that is more likely than not to occur in the
19 absence of an immediate suspension order.”.

20 (b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION
21 PLAN PRIOR TO REVOCATION OR SUSPENSION.—Section
22 304(c) of the Controlled Substances Act (21 U.S.C.
23 824(c)) is amended—

24 (1) by striking “(c) Before” and inserting
25 “(c)(1) Before”; and

1 (2) by adding at the end the following:

2 “(2) Before revoking or suspending a registration
3 pursuant to section 303, the Attorney General shall—

4 “(A) provide—

5 “(i) notice to the registrant of the grounds
6 for revocation or suspension; and

7 “(ii) in the case of any such grounds con-
8 sisting of a violation of law, a specific citation
9 to such law;

10 “(B) give the registrant an opportunity to sub-
11 mit a corrective action plan within a reasonable pe-
12 riod of time to demonstrate how the registrant plans
13 to correct the grounds for revocation or suspension;
14 and

15 “(C) determine whether—

16 “(i) in light of the plan, revocation or sus-
17 pension proceedings should be discontinued or
18 deferred; or

19 “(ii) additional changes need to be made in
20 the corrective action plan.”.

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 Congress—

7 (1) assessing how patient access to medications
8 could be adversely impacted by Federal and State
9 law enforcement activities; and

10 (2) identifying how collaboration between agen-
11 cies and stakeholders can benefit patients and pre-
12 vent diversion and abuse of controlled substances.

13 (b) CONSULTATION.—The report under subsection
14 (a) shall incorporate feedback and recommendations from
15 the following:

16 (1) Patient groups.

17 (2) Pharmacies.

18 (3) Manufacturers of drugs.

19 (4) Common or contract carriers and ware-
20 housemen.

21 (5) Hospitals, physicians, and other health care
22 providers.

23 (6) State attorneys general.

24 (7) Law enforcement officials, including local
25 law enforcement officials.

1 (8) Health benefit plans and entities that pro-
2 vide pharmacy benefit management services on be-
3 half of a health benefit plan.

4 (9) Wholesale drug distributors.

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