

113TH CONGRESS
2D SESSION

H. R. 4069

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 18, 2014

Mr. MARINO (for himself and Mrs. BLACKBURN) 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 2013”.

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) CRIMINAL BACKGROUND CHECKS AND DRUG
21 TESTING FOR EMPLOYEES WITH ACCESS TO CON-
22 TROLLED SUBSTANCES.—

23 (1) REQUIREMENTS.—Section 303 of the Con-
24 trolled Substances Act (21 U.S.C. 823) is amended

1 by inserting before subsection (j) (as added by sub-
2 section (a)(1)) the following:

3 “(i)(1) The Attorney General shall require all reg-
4 istrants under subsections (a), (b), (d), or (e), as a condi-
5 tion of such registration—

6 “(A) to obtain a criminal background check on
7 each of the registrant’s employees who has or will
8 have access to facility areas where controlled sub-
9 stances under the registrant’s possession or control
10 are stored, such as a cage, vault, or safe; and

11 “(B) to perform drug testing on each such em-
12 ployee in accordance with Federal and State law.

13 “(2) The criminal background checks required by
14 paragraph (1) shall be obtained—

15 “(A) periodically, but not more frequently than
16 every 2 years, for all employees of the registrant who
17 are described in paragraph (1)(A); and

18 “(B) at the time of hire, for such employees
19 who are hired after the date of enactment of the En-
20 suring Patient Access and Effective Drug Enforce-
21 ment Act of 2013.

22 “(3) The term ‘drug testing’ means testing designed
23 to detect the illegal use of a controlled substance.”.

1 (2) CONFORMING CHANGE.—Section 304(a) of
2 the Controlled Substances Act (21 U.S.C. 823(a)) is
3 amended—

4 (A) in paragraph (4), by striking “or” at
5 the end;

6 (B) in paragraph (5), by striking the pe-
7 riod at the end and inserting “; or”; and

8 (C) by adding at the end the following:

9 “(6) has failed to comply with the requirements
10 under section 303(i) (relating to criminal back-
11 ground checks and drug testing).”.

12 (3) ALTERNATIVE CIVIL PENALTY FOR FAILURE
13 TO COMPLY WITH CRIMINAL BACKGROUND CHECK
14 AND DRUG TESTING REQUIREMENTS.—

15 (A) PROHIBITED ACT.—Section 402(a) of
16 the Controlled Substances Act (21 U.S.C.
17 842(a)) is amended—

18 (i) in paragraph (14), by striking “or”
19 at the end;

20 (ii) in paragraph (15), by striking the
21 period at the end and inserting “; or”; and

22 (iii) by inserting after paragraph (15)
23 the following:

1 “(16) who is a registrant to fail to comply with
2 the requirements under section 303(i) (relating to
3 criminal background checks and drug testing);”.

4 (B) MAXIMUM CIVIL PENALTY OF
5 \$10,000.—Subsection (c)(1)(B) of the Controlled
6 Substances Act (21 U.S.C. 842(c)(1)(B)) is
7 amended by striking “paragraph (5) or (10)”
8 and inserting “paragraph (5), (10), or (16)”.

9 (4) REGULATIONS, GUIDANCE.—The Attorney
10 General of the United States shall finalize such reg-
11 ulations and guidance as the Attorney General
12 deems necessary to carry out the amendments made
13 by this subsection.

14 (5) APPLICABILITY.—The amendments made
15 by this subsection shall apply beginning on the date
16 that is 2 years after the date of enactment of this
17 Act.

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

22 (1) by striking “(c) Before” and inserting
23 “(c)(1) Before”; and

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

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

3 “(A) provide—

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

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

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

14 “(C) determine whether—

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

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

20 **SEC. 3. COMBATING PRESCRIPTION DRUG ABUSE WORKING**
 21 **GROUP.**

22 (a) ESTABLISHMENT.—There is established the Com-
 23 bating Prescription Drug Abuse Working Group (referred
 24 to in this section as the “Working Group”).

25 (b) MEMBERSHIP.—

1 (1) APPOINTMENT.—

2 (A) IN GENERAL.—Not later than 180
3 days after the date of the enactment of this
4 Act, the President shall appoint each member
5 of the Working Group.

6 (B) COMPOSITION.—The Working Group
7 shall be composed of not more than 20 mem-
8 bers and shall include at least 1 and not more
9 than 3 of each of the following:

10 (i) Public policy experts.

11 (ii) Representatives of the Drug En-
12 forcement Administration.

13 (iii) Representatives of the Food and
14 Drug Administration.

15 (iv) Representatives of the Office of
16 National Drug Control Policy.

17 (v) Representatives of patient groups.

18 (vi) Representatives of pharmacies.

19 (vii) Representatives of manufacturers
20 of drugs.

21 (viii) Representatives of wholesale dis-
22 tributors of drugs.

23 (ix) Representatives of hospitals, phy-
24 sicians, and other health care providers.

1 (x) Representatives of State attorneys
2 general.

3 (xi) Representatives of law enforce-
4 ment officials, including local law enforce-
5 ment officials.

6 (xii) Representatives of health benefits
7 plans and entities that provide pharmacy
8 benefits management services on behalf of
9 a health benefits plans.

10 (2) CO-CHAIRS.—The co-chairs shall be elected
11 by the members of the Working Group. The Work-
12 ing Group shall select for election from the members
13 of the Group two individuals, of whom—

14 (A) one shall be a representative of the
15 Federal Government or a State government;
16 and

17 (B) one shall be a representative of a non-
18 governmental entity.

19 (3) TERM; VACANCIES.—Each member shall be
20 appointed for the life of the Working Group. Any va-
21 cancy in the Working Group shall not affect the
22 powers of the Working Group and shall be filled in
23 the same manner in which the original appointment
24 was made.

1 (4) PAY PROHIBITED.—Members of the Work-
2 ing Group shall serve without pay.

3 (c) MEETINGS.—The Working Group shall meet at
4 the call of the co-chairs. The Working Group shall conduct
5 at least two public meetings, at which the Working Group
6 shall provide opportunity for public comment.

7 (d) DUTIES OF THE WORKING GROUP.—

8 (1) IN GENERAL.—The Working Group shall—

9 (A) review and report to Congress on Fed-
10 eral initiatives with respect to efforts to reduce
11 prescription drug diversion and abuse;

12 (B) identify gaps and opportunities with
13 respect to ensuring the safe use of prescription
14 drugs with the potential for diversion and
15 abuse;

16 (C) examine recommendations to transfer
17 one or more controlled substances from sched-
18 ule III to schedule II under the Controlled Sub-
19 stances Act (21 U.S.C. 801 et seq.) to evalu-
20 ate—

21 (i) the effectiveness of such a transfer
22 in reducing diversion and abuse; and

23 (ii) any effect of such a transfer on
24 access to prescription drugs for legitimate
25 medical purposes; and

1 (D) make recommendations on specific
2 ways to reduce the diversion and abuse of pre-
3 scription drugs.

4 (2) REPORT.—

5 (A) IN GENERAL.—Not later than one year
6 after the date of the enactment of this Act, the
7 Working Group shall issue a report to Congress
8 that describes the efforts of the Working Group
9 to prevent or reduce prescription drug diversion
10 and abuse to ensure that patients continue to
11 have access to medications.

12 (B) RECOMMENDATIONS.—The report de-
13 scribed in subparagraph (A) shall include spe-
14 cific recommendations for the Drug Enforce-
15 ment Administration, the Food and Drug Ad-
16 ministration, and other Federal and State agen-
17 cies, as appropriate, and shall address the fol-
18 lowing topics:

19 (i) Systems for prescription drug
20 monitoring.

21 (ii) Illegal prescription drug Internet
22 sites and facilities that distribute and fill
23 prescriptions indiscriminately.

24 (iii) Facilitating proper disposal of
25 prescription drugs.

1 (iv) Identifying active geographic
2 areas in which prescription drug abuse is
3 prevalent.

4 (v) Ensuring access to prescription
5 drugs for legitimate medical purposes.

6 (vi) Improving collaboration among
7 Federal agencies, especially the Drug En-
8 forcement Administration and the Food
9 and Drug Administration, for purposes of
10 coordinating prevention and enforcement
11 efforts to reduce prescription drug diver-
12 sion and abuse.

13 (vii) Improving collaboration among
14 Federal agencies and State agencies for
15 purposes of coordinating prevention and
16 enforcement efforts to reduce prescription
17 drug diversion and abuse.

18 (viii) The resource needs for law en-
19 forcement with respect to prescription drug
20 abuse.

21 (ix) The need for education of pro-
22 viders, patients, parents, and youth on pre-
23 scription drug abuse.

24 (x) Development of abuse-resistant
25 prescription drug products.

1 (xi) Recommendations for reducing
2 robberies, burglaries, and cargo theft of
3 prescription drugs.

4 (e) POWERS OF THE WORKING GROUP.—

5 (1) HEARINGS.—The Working Group may, for
6 the purpose of carrying out this section, hold hear-
7 ings, sit and act at times and places, take testimony,
8 and receive evidence as the Working Group considers
9 necessary.

10 (2) INFORMATION FROM FEDERAL AGENCIES.—

11 The Working Group may secure directly from any
12 Federal department or agency such information as
13 the Working Group considers necessary to carry out
14 this section. Upon the request of the co-chairs of the
15 Working Group, the head of such department or
16 agency shall furnish such information to the Work-
17 ing Group in a timely manner.

18 (f) TERMINATION OF THE WORKING GROUP.—The
19 Working Group shall terminate two years after the date
20 on which the members are appointed under subsection (b).

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