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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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ensuring Patient Access and Effective Drug Enforcement Act of 2013''.

SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED SUBSTANCES ACT.

(a) DEFINITIONS.—

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

''(j) In this section, the phrase 'consistent with the public health and safety' means having a substantial relationship to this Act's purpose of preventing diversion and abuse of controlled substances.''.

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

(A) by striking ''(d) The Attorney General'' and inserting ''(d)(1) The Attorney General''; and

(B) by adding at the end the following:

''(2) In this subsection, the term 'imminent danger' means a significant and present risk of death or serious bodily harm that is more likely than not to occur in the absence of an immediate suspension order.''.

(b) CRIMINAL BACKGROUND CHECKS AND DRUG TESTING FOR EMPLOYEES WITH ACCESS TO CONTROLLED SUBSTANCES.—

(1) REQUIREMENTS.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended

by inserting before subsection (j) (as added by subsection (a)(1)) the following:

''(i)(1) The Attorney General shall require all registrants under subsections (a), (b), (d), or (e), as a condition of such registration—

''(A) to obtain a criminal background check on each of the registrant's employees who has or will have access to facility areas where controlled substances under the registrant's possession or control are stored, such as a cage, vault, or safe; and

''(B) to perform drug testing on each such employee in accordance with Federal and State law.

''(2) The criminal background checks required by paragraph (1) shall be obtained—

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

''(B) at the time of hire, for such employees who are hired after the date of enactment of the Ensuring Patient Access and Effective Drug Enforcement Act of 2013.

''(3) The term 'drug testing' means testing designed to detect the illegal use of a controlled substance.''.

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

(A) in paragraph (4), by striking ''or'' at the end;

(B) in paragraph (5), by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(6) has failed to comply with the requirements under section 303(i) (relating to criminal background checks and drug testing).''.

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

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

(i) in paragraph (14), by striking ''or'' at the end;

(ii) in paragraph (15), by striking the period at the end and inserting ''; or''; and

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

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

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

(4) REGULATIONS, GUIDANCE.—The Attorney General of the United States shall finalize such regulations and guidance as the Attorney General deems necessary to carry out the amendments made by this subsection.

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

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

(1) by striking ''(c) Before'' and inserting ''(c)(1) Before''; and

(2) by adding at the end the following:

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

''(A) provide—

''(i) notice to the registrant of the grounds for revocation or suspension; and

''(ii) in the case of any such grounds consisting of a violation of law, a specific citation to such law;

''(B) give the registrant an opportunity to submit a corrective action plan within a reasonable period of time to demonstrate how the registrant plans to correct the grounds for revocation or suspension; and

''(C) determine whether—

''(i) in light of the plan, revocation or suspension proceedings should be discontinued or deferred; or

''(ii) additional changes need to be made in the corrective action plan.''.

SEC. 3. COMBATING PRESCRIPTION DRUG ABUSE WORKING GROUP.

(a) ESTABLISHMENT.—There is established the Combating Prescription Drug Abuse Working Group (referred to in this section as the ''Working Group'').

(b) MEMBERSHIP.—

(1) APPOINTMENT.—

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

(B) COMPOSITION.—The Working Group shall be composed of not more than 20 members and shall include at least 1 and not more than 3 of each of the following:

(i) Public policy experts.

(ii) Representatives of the Drug Enforcement Administration.

(iii) Representatives of the Food and Drug Administration.

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

(v) Representatives of patient groups.

(vi) Representatives of pharmacies.

(vii) Representatives of manufacturers of drugs.

(viii) Representatives of wholesale distributors of drugs.

(ix) Representatives of hospitals, physicians, and other health care providers.

(x) Representatives of State attorneys general.

(xi) Representatives of law enforcement officials, including local law enforcement officials.

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

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

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

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

(3) TERM; VACANCIES.—Each member shall be appointed for the life of the Working Group. Any vacancy in the Working Group shall not affect the powers of the Working Group and shall be filled in the same manner in which the original appointment was made.

(4) PAY PROHIBITED.—Members of the Working Group shall serve without pay.

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

(d) DUTIES OF THE WORKING GROUP.—

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

(A) review and report to Congress on Federal initiatives with respect to efforts to reduce prescription drug diversion and abuse;

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

(C) examine recommendations to transfer one or more controlled substances from schedule III to schedule II under the Controlled Substances Act (21 U.S.C. 801 et seq.) to evaluate—

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

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

(D) make recommendations on specific ways to reduce the diversion and abuse of prescription drugs.

(2) REPORT.—

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

(B) RECOMMENDATIONS.—The report described in subparagraph (A) shall include specific recommendations for the Drug Enforcement Administration, the Food and Drug Administration, and other Federal and State agencies, as appropriate, and shall address the following topics:

(i) Systems for prescription drug monitoring.

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

(iii) Facilitating proper disposal of prescription drugs.

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

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

(vi) Improving collaboration among Federal agencies, especially the Drug Enforcement Administration and the Food and Drug Administration, for purposes of coordinating prevention and enforcement efforts to reduce prescription drug diversion and abuse.

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

(viii) The resource needs for law enforcement with respect to prescription drug abuse.

(ix) The need for education of providers, patients, parents, and youth on prescription drug abuse.

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

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

(e) POWERS OF THE WORKING GROUP.—

(1) HEARINGS.—The Working Group may, for the purpose of carrying out this section, hold hearings, sit and act at times and places, take testimony, and receive evidence as the Working Group considers necessary.

(2) INFORMATION FROM FEDERAL AGENCIES.—The Working Group may secure directly from any Federal department or agency such information as the Working Group considers necessary to carry out this section. Upon the request of the co-chairs of the Working Group, the head of such department or agency shall furnish such information to the Working Group in a timely manner.

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

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