AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

I

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.

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 2014".

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) 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. REPORT TO CONGRESS ON EFFECTS OF LAW ENFORCEMENT ACTIVITIES ON PATIENT ACCESS TO MEDICATIONS.

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

Human Services, acting through the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, and in consultation with the Administrator of the Drug Enforcement Administration and the Director of National Drug Control Policy, shall submit a report to the Congress—

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

(2) identifying how collaboration between agencies and stakeholders can benefit patients and prevent diversion and abuse of controlled substances.

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

(1) Patient groups.

(2) Pharmacies.

(3) Manufacturers of drugs.

(4) Common or contract carriers and warehousemen.

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

(6) State attorneys general.

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

(8) Health benefit plans and entities that provide pharmacy benefit management services on behalf of a health benefit plan.

(9) Wholesale drug distributors.

○