AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

S. 483

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mr. HATCH (for himself and Mr. WHITEHOUSE)

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ensuring Patient Access and Effective Drug Enforcement Act of 2015''.

SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED SUBSTANCES ACT.

(a) DEFINITIONS.—

(1) FACTORS AS MAY BE RELEVANT TO AND 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:

''(i) In this section, the phrase 'factors as may be relevant to and consistent with the public health and safety' means factors that are relevant to and consistent with the findings contained in section 101.''.

(2) IMMINENT DANGER TO THE PUBLIC HEALTH OR SAFETY.—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 phrase 'imminent danger to the public health or safety' means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this title or title III, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.''.

(b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN PRIOR TO REVOCATION OR SUSPENSION.—Sub-

section (c) of section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended—

(1) by striking the last two sentences;

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

(3) by adding at the end the following:

''(2) An order to show cause under paragraph (1) shall—

''(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

''(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

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

''(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

"(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5, United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States.

"(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).".

SEC. 3. REPORT TO CONGRESS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Agency for Healthcare Research and Quality, and the Director of the Centers for Disease Control and Prevention, in coordination with the Administrator of the Drug Enforcement Administration and in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, shall submit a report to the Committee on the Judiciary of the House of Representatives, the Committee on Energy and Commerce of the House of Representatives, the Committee on the Judiciary of the Sen-

ate, and the Committee on Health, Education, Labor, and Pensions of the Senate identifying—

(1) obstacles to legitimate patient access to controlled substances;

(2) issues with diversion of controlled substances;

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

(4) the availability of medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing, and any gaps that should be addressed;

(5) beneficial enhancements to State prescription drug monitoring programs, including enhancements to require comprehensive prescriber input and to expand access to the programs for appropriate authorized users; and

(6) steps to improve reporting requirements so that the public and Congress have more information regarding prescription opioids, such as the volume and formulation of prescription opioids prescribed annually, the dispensing of such prescription opioids, and outliers and trends within large data sets.

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

(1) Patient groups.

(2) Pharmacies.

(3) Drug manufacturers.

(4) Common or contract carriers and warehousemen.

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

(6) State attorneys general.

(7) Federal, State, local, and tribal law enforcement agencies.

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

(9) Wholesale drug distributors.

(10) Veterinarians.

(11) Professional medical societies and boards.

(12) State and local public health authorities.

(13) Health services research organizations.