

# Calendar No. 368

114TH CONGRESS  
2D SESSION

# S. 483

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

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2015

Mr. HATCH (for himself, Mr. WHITEHOUSE, Mr. RUBIO, Mr. VITTER, and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

FEBRUARY 11, 2016

Reported by Mr. GRASSLEY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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## 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 2015”.

1 **SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED**  
 2 **SUBSTANCES ACT.**

3 (a) DEFINITIONS.—

4 (1) FACTORS AS MAY BE RELEVANT TO AND  
 5 CONSISTENT WITH THE PUBLIC HEALTH AND SAFE-  
 6 TY.—Section 303 of the Controlled Substances Act  
 7 (21 U.S.C. 823) is amended by adding at the end  
 8 the following:

9 “(i) In this section, the phrase ‘factors as may be rel-  
 10 evant to and consistent with the public health and safety’  
 11 means factors that are relevant to and consistent with the  
 12 findings contained in section 101.”.

13 (2) IMMINENT DANGER TO THE PUBLIC  
 14 HEALTH OR SAFETY.—Section 304(d) of the Con-  
 15 trolled Substances Act (21 U.S.C. 824(d)) is amend-  
 16 ed—

17 (A) by striking “(d) The Attorney Gen-  
 18 eral” and inserting “(d)(1) The Attorney Gen-  
 19 eral”; and

20 (B) by adding at the end the following:

21 “(2) In this subsection, the phrase ‘imminent danger  
 22 to the public health or safety’ means that, in the absence  
 23 of an immediate suspension order, controlled substances  
 24 will continue to be distributed or dispensed by a registrant  
 25 who knows or should know through fulfilling the obliga-  
 26 tions of the registrant under this Act—

1           “(A) the dispensing is outside the usual course  
2 of professional practice;

3           “(B) the distribution or dispensing poses a  
4 present or foreseeable risk of adverse health con-  
5 sequences or death due to the abuse or misuse of the  
6 controlled substances; or

7           “(C) the controlled substances will continue to  
8 be diverted outside of legitimate distribution chan-  
9 nels.”.

10       (b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION  
11 PLAN PRIOR TO REVOCATION OR SUSPENSION.—Sub-  
12 section (e) of section 304 of the Controlled Substances Act  
13 (21 U.S.C. 824) is amended—

14           (1) by striking the last two sentences;

15           (2) by striking “(e) Before” and inserting  
16 “(e)(1) Before”; and

17           (3) by adding at the end the following:

18       “(2) An order to show cause under paragraph (1)  
19 shall—

20           “(A) contain a statement of the basis for the  
21 denial, revocation, or suspension, including specific  
22 citations to any laws or regulations alleged to be vio-  
23 lated by the applicant or registrant;

24           “(B) direct the applicant or registrant to ap-  
25 pear before the Attorney General at a time and

1 place stated in the order, but not less than 30 days  
 2 after the date of receipt of the order, and

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

6 “(3) Upon review of any corrective action plan sub-  
 7 mitted by an applicant or registrant pursuant to para-  
 8 graph (2), the Attorney General shall determine whether  
 9 denial, revocation or suspension proceedings should be dis-  
 10 continued, or deferred for the purposes of modification,  
 11 amendment, or clarification to such plan.

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

18 “(5) The requirements of this subsection shall not  
 19 apply to the issuance of an immediate suspension order  
 20 under subsection (d).”.

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 1 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, in coordination with the Ad-  
4 ministrator of the Drug Enforcement Administration and  
5 in consultation with the Secretary of Defense and the Sec-  
6 retary of Veterans Affairs, shall submit a report to the  
7 Committee on the Judiciary of the House of Representa-  
8 tives, the Committee on Energy and Commerce of the  
9 House of Representatives, the Committee on the Judiciary  
10 of the Senate, and the Committee on Health, Education,  
11 Labor, and Pensions of the Senate identifying—

12           (1) obstacles to legitimate patient access to con-  
13           trolled substances;

14           (2) issues with diversion of controlled sub-  
15           stances; and

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

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

23           (1) Patient groups.

24           (2) Pharmacies.

25           (3) Drug manufacturers.

1           ~~(4) Common or contract carriers and ware-~~  
2           ~~housemen.~~

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

5           ~~(6) State attorneys general.~~

6           ~~(7) Federal, State, local, and tribal law enforce-~~  
7           ~~ment agencies.~~

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

11          ~~(9) Wholesale drug distributors.~~

12          ~~(10) Veterinarians.~~

13   **SECTION 1. SHORT TITLE.**

14           *This Act may be cited as the “Ensuring Patient Access*  
15   *and Effective Drug Enforcement Act of 2016”.*

16   **SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED SUB-**  
17                                   **STANCES ACT.**

18           *(a) DEFINITIONS.—*

19                   *(1) FACTORS AS MAY BE RELEVANT TO AND CON-*  
20                   *SISTENT WITH THE PUBLIC HEALTH AND SAFETY.—*

21                   *Section 303 of the Controlled Substances Act (21*  
22                   *U.S.C. 823) is amended by adding at the end the fol-*  
23                   *lowing:*

24                   *“(j) In this section, the phrase ‘factors as may be rel-*  
25                   *evant to and consistent with the public health and safety’*

1 *means factors that are relevant to and consistent with the*  
 2 *findings contained in section 101.”*

3           (2) *IMMINENT DANGER TO THE PUBLIC HEALTH*  
 4           *OR SAFETY.—Section 304(d) of the Controlled Sub-*  
 5           *stances Act (21 U.S.C. 824(d)) is amended—*

6                   (A) *by striking “(d) The Attorney General”*  
 7                   *and inserting “(d)(1) The Attorney General”;*  
 8                   *and*

9                   (B) *by adding at the end the following:*

10           *“(2) In this subsection, the phrase ‘imminent danger*  
 11 *to the public health or safety’ means that, due to the failure*  
 12 *of the registrant to maintain effective controls against di-*  
 13 *version or otherwise comply with the obligations of a reg-*  
 14 *istrant under this title or title III, there is a substantial*  
 15 *likelihood of an immediate threat that death, serious bodily*  
 16 *harm, or abuse of a controlled substance will occur in the*  
 17 *absence of an immediate suspension of the registration.”.*

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

22                   (1) *by striking the last three sentences;*

23                   (2) *by striking “(c) Before” and inserting “(c)(1)*  
 24 *Before”; and*

25                   (3) *by adding at the end the following:*

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

3               “(A) *contain a statement of the basis for the de-*  
4  *denial, revocation, or suspension, including specific ci-*  
5  *tations to any laws or regulations alleged to be vio-*  
6  *lated by the applicant or registrant;*

7               “(B) *direct the applicant or registrant to appear*  
8  *before the Attorney General at a time and place stat-*  
9  *ed in the order, but not less than 30 days after the*  
10  *date of receipt of the order; and*

11               “(C) *notify the applicant or registrant of the op-*  
12  *portunity to submit a corrective action plan on or be-*  
13  *fore the date of appearance.*

14       “(3) *Upon review of any corrective action plan sub-*  
15  *mitted by an applicant or registrant pursuant to para-*  
16  *graph (2), the Attorney General shall determine whether de-*  
17  *nial, revocation, or suspension proceedings should be dis-*  
18  *continued, or deferred for the purposes of modification,*  
19  *amendment, or clarification to such plan.*

20       “(4) *Proceedings to deny, revoke, or suspend shall be*  
21  *conducted pursuant to this section in accordance with sub-*  
22  *chapter II of chapter 5 of title 5, United States Code. Such*  
23  *proceedings shall be independent of, and not in lieu of,*  
24  *criminal prosecutions or other proceedings under this title*  
25  *or any other law of the United States.*

1       “(5) *The requirements of this subsection shall not*  
2 *apply to the issuance of an immediate suspension order*  
3 *under subsection (d).”.*

4 **SEC. 3. REPORT TO CONGRESS.**

5       (a) *IN GENERAL.*—*Not later than 1 year after the date*  
6 *of enactment of this Act, the Secretary of Health and*  
7 *Human Services, acting through the Commissioner of Food*  
8 *and Drugs, the Administrator of the Substance Abuse and*  
9 *Mental Health Services Administration, the Director of the*  
10 *Agency for Healthcare Research and Quality, and the Di-*  
11 *rector of the Centers for Disease Control and Prevention,*  
12 *in coordination with the Administrator of the Drug En-*  
13 *forcement Administration and in consultation with the Sec-*  
14 *retary of Defense and the Secretary of Veterans Affairs,*  
15 *shall submit a report to the Committee on the Judiciary*  
16 *of the House of Representatives, the Committee on Energy*  
17 *and Commerce of the House of Representatives, the Com-*  
18 *mittee on the Judiciary of the Senate, and the Committee*  
19 *on Health, Education, Labor, and Pensions of the Senate*  
20 *identifying—*

21               (1) *obstacles to legitimate patient access to con-*  
22 *trolled substances;*

23               (2) *issues with diversion of controlled substances;*

24               (3) *how collaboration between Federal, State,*  
25 *local, and tribal law enforcement agencies and the*

1        *pharmaceutical industry can benefit patients and*  
2        *prevent diversion and abuse of controlled substances;*

3            *(4) the availability of medical education, train-*  
4        *ing opportunities, and comprehensive clinical guid-*  
5        *ance for pain management and opioid prescribing,*  
6        *and any gaps that should be addressed;*

7            *(5) beneficial enhancements to State prescription*  
8        *drug monitoring programs, including enhancements*  
9        *to require comprehensive prescriber input and to ex-*  
10       *pend access to the programs for appropriate author-*  
11       *ized users; and*

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

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

21            *(1) Patient groups.*

22            *(2) Pharmacies.*

23            *(3) Drug manufacturers.*

24            *(4) Common or contract carriers and warehouse-*  
25       *men.*

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

3           (6) *State attorneys general.*

4           (7) *Federal, State, local, and tribal law enforce-*  
5           *ment agencies.*

6           (8) *Health insurance providers and entities that*  
7           *provide pharmacy benefit management services on be-*  
8           *half of a health insurance provider.*

9           (9) *Wholesale drug distributors.*

10          (10) *Veterinarians.*

11          (11) *Professional medical societies and boards.*

12          (12) *State and local public health authorities.*

13          (13) *Health services research organizations.*

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2<sup>D</sup> SESSION

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**A BILL**

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