

115TH CONGRESS  
2D SESSION

# S. 2838

To amend the Controlled Substances Act to require the Drug Enforcement Administration to report certain information on distribution of opioids, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

MAY 15, 2018

Mrs. FEINSTEIN (for herself, Mr. GRASSLEY, Mrs. CAPITO, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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## A BILL

To amend the Controlled Substances Act to require the Drug Enforcement Administration to report certain information on distribution of opioids, 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 “Using Data to Prevent  
5       Opioid Diversion Act of 2018”.

6       **SEC. 2. FINDINGS.**

7       Congress finds the following:

1           (1) In 2016, there were nearly 64,000 drug  
2 overdose deaths in the United States. More than  
3 42,000 of these deaths were opioid-related.

4           (2) The regulations promulgated under the  
5 Controlled Substances Act (21 U.S.C. 801 et seq.)  
6 require drug manufacturers and distributors to—

7                 (A) provide effective controls against the  
8 diversion of controlled substances;

9                 (B) detect and disclose suspicious orders to  
10 the Drug Enforcement Administration; and

11                 (C) keep complete and accurate records re-  
12 lating to the manufacture or distribution of  
13 controlled substances.

14           (3) Despite the requirements described in para-  
15 graph (2), it has been publicly reported that between  
16 2006 and 2016, nearly 21,000,000 opioids were dis-  
17 tributed to 2 pharmacies in Williamson, West Vir-  
18 ginia, which has a population of approximately  
19 3,000. It has been further reported that between  
20 2007 and 2008, nearly 9,000,000 pills were distrib-  
21 uted to a single pharmacy in Kermit, West Virginia,  
22 which has a population of 392.

23           (4) Similarly, it has been publicly reported that  
24 780,000,000 oxycodone and hydrocodone pills were  
25 distributed to pharmacies throughout West Virginia

1       between 2007 and 2012. In the same period, more  
2       than 1,700 people in the State died from overdoses  
3       of these 2 substances.

4           (5) Drug manufacturers and distributors are  
5       required to report the sale, delivery or other disposal  
6       of narcotics to the Drug Enforcement Administra-  
7       tion through the Automated Reports and Consoli-  
8       dated Ordering System.

9           (6) Notwithstanding the reporting requirement  
10      described in paragraph (5), the Drug Enforcement  
11      Administration does not disclose the total quantity  
12      and type of opioids distributed to a single pharmacy  
13      or practitioner with those manufacturers and dis-  
14      tributors who are required to input information into  
15      the Automated Reports and Consolidated Ordering  
16      System. This creates a barrier to identifying and  
17      stopping potentially suspicious orders.

18          (7) Although manufacturers and distributors  
19      are already required to provide effective controls  
20      against the diversion of controlled substances, this  
21      lack of data sharing may create a barrier to better  
22      identifying and stopping potentially suspicious or-  
23      ders.

24          (8) On an annual basis, the Attorney General  
25      of the United States is statutorily required to share

1 the controlled substance or substances in schedule II  
2 that have the highest rates of abuse and to prepare  
3 and make available reports on the distribution pat-  
4 terns of such substances, with State regulatory, li-  
5 censing, and law enforcement agencies. The Attor-  
6 ney General of the United States has entered into  
7 data sharing agreements with the attorneys general  
8 of the vast majority of States, Puerto Rico, and the  
9 District of Colombia to share, pursuant to State law  
10 and policy, data obtained from State prescription  
11 drug monitoring programs and other sources.

12 (9) To further reduce barriers associated with  
13 identifying suspicious patterns and stopping the di-  
14 version of opioids, the remaining States and terri-  
15 tories of the United States should enter into similar  
16 agreements with, and to the greatest extent practical  
17 share data obtained from State prescription drug  
18 monitoring programs with, the Attorney General of  
19 the United States.

20 **SEC. 3. PURPOSE.**

21 (a) IN GENERAL.—The purpose of this Act is to pro-  
22 vide drug manufacturers and distributors with access to  
23 anonymized information through the Automated Reports  
24 and Consolidated Ordering System to help drug manufac-

1   turers and distributors identify, report, and stop sus-  
 2   picious orders of opioids and reduce diversion rates.

3       (b) RULE OF CONSTRUCTION.—Nothing in this Act  
 4   should be construed to absolve a drug manufacturer, drug  
 5   distributor, or other Drug Enforcement Administration  
 6   registrant from the responsibility of the manufacturer, dis-  
 7   tributor, or other registrant to—

8           (1) identify, report, and stop suspicious orders;

9       or

10          (2) use all available sources of information to  
 11   determine—

12           (A) the legitimacy of a customer’s order;

13       and

14           (B) whether or not an order described in  
 15   subparagraph (A) is suspicious.

16   **SEC. 4. AMENDMENTS.**

17       (a) RECORDS AND REPORTS OF REGISTRANTS.—Sec-  
 18   tion 307 of the Controlled Substances Act (21 U.S.C. 827)  
 19   is amended—

20          (1) by redesignating subsections (f), (g), and  
 21   (h) as subsections (g), (h), and (i), respectively;

22          (2) by inserting after subsection (e) the fol-  
 23   lowing:

24       “(f)(1) The Attorney General shall, not less fre-  
 25   quently than quarterly, make the following information

1 available to manufacturer and distributor registrants  
2 through the Automated Reports and Consolidated Order-  
3 ing System, or any subsequent automated system devel-  
4 oped by the Drug Enforcement Administration to monitor  
5 selected controlled substances:

6           “(A) The total number of distributor reg-  
7 istrants that distribute controlled substances to a  
8 pharmacy or practitioner registrant, aggregated by  
9 the name and address of each pharmacy and practi-  
10 tioner registrant.

11           “(B) The total quantity and type of opioids dis-  
12 tributed, listed by Administration Controlled Sub-  
13 stances Code Number, to each pharmacy and practi-  
14 tioner registrant described in subparagraph (A).

15           “(2) The information required to be made available  
16 under paragraph (1) shall be made available not later than  
17 the 15th day of the first month following the quarter to  
18 which the information relates.

19           “(3)(A) All registered manufacturers and distributors  
20 shall be responsible for reviewing the information made  
21 available by the Attorney General under this subsection.

22           “(B) In determining whether to initiate proceedings  
23 under this title against a registered manufacturer or dis-  
24 tributor based on the failure of the registrant to maintain  
25 effective controls against diversion or otherwise comply

1 with the requirements of this title or the regulations issued  
2 thereunder, the Attorney General may take into account  
3 that the information made available under this subsection  
4 was available to the registrant.”; and

5 (3) by inserting after subsection (i), as so re-  
6 designated, the following:

7 “(j) All of the reports required under this section  
8 shall be provided in an electronic format.”.

9 (b) COOPERATIVE ARRANGEMENTS.—Section 503 of  
10 the Controlled Substances Act (21 U.S.C. 873) is amend-  
11 ed—

12 (1) by striking subsection (c) and inserting the  
13 following:

14 “(c)(1) The Attorney General shall, once every 6  
15 months, prepare and make available to regulatory, licens-  
16 ing, attorneys general, and law enforcement agencies of  
17 States a standardized report containing descriptive and  
18 analytic information on the actual distribution patterns,  
19 as gathered through the Automated Reports and Consoli-  
20 dated Ordering System, or any subsequent automated sys-  
21 tem, pursuant to section 307 and which include detailed  
22 amounts, outliers, and trends of distributor and pharmacy  
23 registrants, in such States for the controlled substances  
24 contained in schedule II, which, in the discretion of the

1 Attorney General, are determined to have the highest  
2 abuse.

3 “(2) If the Attorney General publishes the report de-  
4 scribed in paragraph (1) once every 6 months as required  
5 under paragraph (1), nothing in this subsection shall be  
6 construed to bring an action in any court to challenge the  
7 sufficiency of the information or to compel the Attorney  
8 General to produce any documents or reports referred to  
9 in this subsection.”.

10 (c) CIVIL AND CRIMINAL PENALTIES.—Section 402  
11 of the Controlled Substances Act (21 U.S.C. 842) is  
12 amended—

13 (1) in subsection (a)—

14 (A) in paragraph (15), by striking “or” at  
15 the end;

16 (B) in paragraph (16), by striking the pe-  
17 riod at the end and inserting “; or”; and

18 (C) by inserting after paragraph (16) the  
19 following:

20 “(17) in the case of a registered manufacturer  
21 or distributor of opioids, to fail to review the most  
22 recent information made available by the Attorney  
23 General in accordance with section 307(f) before  
24 each distribution of a controlled substance referred  
25 to in such information.”; and



1 (2) in subsection (c)—

2 (A) in paragraph (1), by striking subpara-  
3 graph (B) and inserting the following:

4 “(B)(i) Except as provided in clause (ii), in the case  
5 of a violation of paragraph (5), (10), or (17) of subsection  
6 (a), the penalty shall not exceed \$10,000.

7 “(ii) In the case of a violation described in clause (i)  
8 committed by a registered manufacturer or distributor of  
9 opioids and related to the reporting of suspicious orders  
10 for opioids, failing to maintain effective controls against  
11 diversion of opioids, or failing to review the most recent  
12 information made available by the Attorney General in ac-  
13 cordance with section 307(f), the penalty shall not exceed  
14 \$100,000.”; and

15 (B) in paragraph (2)—

16 (i) in subparagraph (A), by inserting  
17 “or (D)” after “subparagraph (B)”; and

18 (ii) by adding at the end the fol-  
19 lowing:

20 “(D) In the case of a violation described in subpara-  
21 graph (A) that was a violation of paragraph (5), (10), or  
22 (17) of subsection (a) committed by a registered manufac-  
23 turer or distributor of opioids that relates to the reporting  
24 of suspicious orders for opioids, failing to maintain effec-  
25 tive controls against diversion of opioids, or failing to re-

1 view the most recent information made available by the  
2 Attorney General in accordance with section 307(f), the  
3 criminal fine under title 18, United States Code, shall not  
4 exceed \$500,000.”.

5 **SEC. 5. REPORT.**

6 Not later than 1 year after the date of enactment  
7 of this Act, the Attorney General shall submit to Congress  
8 a report that provides information about how the Attorney  
9 General is using data in the Automation of Reports and  
10 Consolidated Orders System to identify and stop sus-  
11 picious activity, including whether the Attorney General  
12 is looking at aggregate orders from individual pharmacies  
13 to multiple distributors that in total are suspicious, even  
14 if no individual order rises to the level of a suspicious  
15 order to a given distributor.

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