

Calendar No. 476

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.

IN THE SENATE OF THE UNITED STATES

MAY 15, 2018

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

JUNE 19, 2018

Reported by Mr. GRASSLEY, with an amendment

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

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”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) In 2016, there were nearly 64,000 drug
4 overdose deaths in the United States. More than
5 42,000 of these deaths were opioid-related.

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

9 (A) provide effective controls against the
10 diversion of controlled substances;

11 (B) detect and disclose suspicious orders to
12 the Drug Enforcement Administration; and

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

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

25 (4) Similarly, it has been publicly reported that
26 780,000,000 oxycodone and hydrocodone pills were

1 distributed to pharmacies throughout West Virginia
2 between 2007 and 2012. In the same period, more
3 than 1,700 people in the State died from overdoses
4 of these 2 substances.

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

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

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

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

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

22 **SEC. 3. PURPOSE.**

23 (a) IN GENERAL.—The purpose of this Act is to pro-
24 vide drug manufacturers and distributors with access to
25 anonymized information through the Automated Reports

1 and Consolidated Ordering System to help drug manufac-
 2 turers and distributors identify, report, and stop sus-
 3 picious orders of opioids and reduce diversion rates.

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

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

10 or

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

13 (A) the legitimacy of a customer's order;

14 and

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

17 **SEC. 4. AMENDMENTS.**

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

21 (1) by redesignating subsections (f), (g), and

22 (h) as subsections (g), (h), and (i), respectively;

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

1 “(f)(1) The Attorney General shall, not less fre-
2 quently than quarterly, make the following information
3 available to manufacturer and distributor registrants
4 through the Automated Reports and Consolidated Order-
5 ing System, or any subsequent automated system devel-
6 oped by the Drug Enforcement Administration to monitor
7 selected controlled substances:

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

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

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

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

24 “(B) In determining whether to initiate proceedings
25 under this title against a registered manufacturer or dis-

1 tributor based on the failure of the registrant to maintain
 2 effective controls against diversion or otherwise comply
 3 with the requirements of this title or the regulations issued
 4 thereunder, the Attorney General may take into account
 5 that the information made available under this subsection
 6 was available to the registrant.”; and

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

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

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

14 (1) by striking subsection (c) and inserting the
 15 following:

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

1 contained in schedule H, which, in the discretion of the
 2 Attorney General, are determined to have the highest
 3 abuse.

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

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

14 (1) in subsection (a)—

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

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

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

21 “(17) in the case of a registered manufacturer
 22 or distributor of opioids, to fail to review the most
 23 recent information made available by the Attorney
 24 General in accordance with section 307(f) before

1 each distribution of a controlled substance referred
 2 to in such information.”; and

3 ~~(2) in subsection (c)—~~

4 ~~(A) in paragraph (1), by striking subpara-~~
 5 ~~graph (B) and inserting the following:~~

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

9 ~~“(ii) In the case of a violation described in clause (i)~~
 10 ~~committed by a registered manufacturer or distributor of~~
 11 ~~opioids and related to the reporting of suspicious orders~~
 12 ~~for opioids; failing to maintain effective controls against~~
 13 ~~diversion of opioids; or failing to review the most recent~~
 14 ~~information made available by the Attorney General in ac-~~
 15 ~~cordance with section 307(f), the penalty shall not exceed~~
 16 ~~\$100,000.”; and~~

17 ~~(B) in paragraph (2)—~~

18 ~~(i) in subparagraph (A), by inserting~~
 19 ~~“or (D)” after “subparagraph (B)”;~~ and

20 ~~(ii) by adding at the end the fol-~~
 21 ~~lowing:~~

22 ~~“(D) In the case of a violation described in subpara-~~
 23 ~~graph (A) that was a violation of paragraph (5), (10), or~~
 24 ~~(17) of subsection (a) committed by a registered manufac-~~
 25 ~~turer or distributor of opioids that relates to the reporting~~

1 of suspicious orders for opioids; failing to maintain effective controls against diversion of opioids; or failing to review the most recent information made available by the Attorney General in accordance with section 307(f), the criminal fine under title 18, United States Code, shall not exceed \$500,000.”.

7 **SEC. 5. REPORT.**

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

18 **SECTION 1. SHORT TITLE.**

19 *This Act may be cited as the “Using Data to Prevent*
20 *Opioid Diversion Act of 2018”.*

21 **SEC. 2. FINDINGS.**

22 *Congress finds the following:*

23 *(1) In 2016, there were nearly 64,000 drug over-*
24 *dose deaths in the United States. More than 42,000*
25 *of these deaths were opioid-related.*

1 (2) *The regulations promulgated under the Con-*
2 *trolled Substances Act (21 U.S.C. 801 et seq.) require*
3 *drug manufacturers and distributors to—*

4 (A) *provide effective controls against the di-*
5 *version of controlled substances;*

6 (B) *detect and disclose suspicious orders to*
7 *the Drug Enforcement Administration; and*

8 (C) *keep complete and accurate records re-*
9 *lating to the manufacture or distribution of con-*
10 *trolled substances.*

11 (3) *Despite the requirements described in para-*
12 *graph (2), it has been publicly reported that between*
13 *2006 and 2016, nearly 21,000,000 opioids were dis-*
14 *tributed to 2 pharmacies in Williamson, West Vir-*
15 *ginia, which has a population of approximately*
16 *3,000. It has been further reported that between 2007*
17 *and 2008, nearly 9,000,000 pills were distributed to*
18 *a single pharmacy in Kermit, West Virginia, which*
19 *has a population of 392.*

20 (4) *Similarly, it has been publicly reported that*
21 *780,000,000 oxycodone and hydrocodone pills were*
22 *distributed to pharmacies throughout West Virginia*
23 *between 2007 and 2012. In the same period, more*
24 *than 1,700 people in the State died from overdoses of*
25 *these 2 substances.*

1 (5) *Drug manufacturers and distributors are re-*
2 *quired to report the sale, delivery or other disposal of*
3 *narcotics to the Drug Enforcement Administration*
4 *through the Automated Reports and Consolidated Or-*
5 *ders System.*

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

15 (7) *Although manufacturers and distributors are*
16 *already required to provide effective controls against*
17 *the diversion of controlled substances, this lack of data*
18 *sharing may create a barrier to better identifying and*
19 *stopping potentially suspicious orders.*

20 (8) *On an annual basis, the Attorney General of*
21 *the United States is statutorily required to share the*
22 *controlled substance or substances in schedule II that*
23 *have the highest rates of abuse and to prepare and*
24 *make available reports on the distribution patterns of*
25 *such substances, with State regulatory, licensing, and*

1 *law enforcement agencies. The Attorney General of the*
2 *United States has entered into data sharing agree-*
3 *ments with the attorneys general of the vast majority*
4 *of States, Puerto Rico, and the District of Colombia*
5 *to share, pursuant to State law and policy, data ob-*
6 *tained from State prescription drug monitoring pro-*
7 *grams and other sources.*

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

16 **SEC. 3. PURPOSE.**

17 *(a) IN GENERAL.—The purpose of this Act is to pro-*
18 *vide drug manufacturers and distributors with access to*
19 *anonymized information through the Automated Reports*
20 *and Consolidated Orders System to help drug manufactur-*
21 *ers and distributors identify, report, and stop suspicious*
22 *orders of opioids and reduce diversion rates.*

23 *(b) RULE OF CONSTRUCTION.—Nothing in this Act*
24 *should be construed to absolve a drug manufacturer, drug*
25 *distributor, or other Drug Enforcement Administration reg-*

1 *istrant from the responsibility of the manufacturer, dis-*
 2 *tributor, or other registrant to—*

3 *(1) identify, stop, and report suspicious orders;*

4 *or*

5 *(2) maintain effective controls against diversion*
 6 *in accordance with section 303 of the Controlled Sub-*
 7 *stances Act (21 U.S.C. 823) or any successor law or*
 8 *associated regulation.*

9 **SEC. 4. AMENDMENTS.**

10 *(a) RECORDS AND REPORTS OF REGISTRANTS.—Sec-*
 11 *tion 307 of the Controlled Substances Act (21 U.S.C. 827)*
 12 *is amended—*

13 *(1) by redesignating subsections (f), (g), and (h)*
 14 *as subsections (g), (h), and (i), respectively;*

15 *(2) by inserting after subsection (e) the following:*

16 *“(f)(1) The Attorney General shall, not less frequently*
 17 *than quarterly, make the following information available*
 18 *to manufacturer and distributor registrants through the*
 19 *Automated Reports and Consolidated Orders System, or*
 20 *any subsequent automated system developed by the Drug*
 21 *Enforcement Administration to monitor selected controlled*
 22 *substances:*

23 *“(A) The total number of distributor registrants*
 24 *that distribute controlled substances to a pharmacy or*

1 *practitioner registrant, aggregated by the name and*
2 *address of each pharmacy and practitioner registrant.*

3 *“(B) The total quantity and type of opioids dis-*
4 *tributed, listed by Administration Controlled Sub-*
5 *stances Code Number, to each pharmacy and practi-*
6 *tioner registrant described in subparagraph (A).*

7 *“(2) The information required to be made available*
8 *under paragraph (1) shall be made available not later than*
9 *the 15th day of the first month following the quarter to*
10 *which the information relates.*

11 *“(3)(A) All registered manufacturers and distributors*
12 *shall be responsible for reviewing the information made*
13 *available by the Attorney General under this subsection.*

14 *“(B) In determining whether to initiate proceedings*
15 *under this title against a registered manufacturer or dis-*
16 *tributor based on the failure of the registrant to maintain*
17 *effective controls against diversion or otherwise comply with*
18 *the requirements of this title or the regulations issued there-*
19 *under, the Attorney General may take into account that the*
20 *information made available under this subsection was*
21 *available to the registrant.”; and*

22 *(3) by inserting after subsection (i), as so redes-*
23 *ignated, the following:*

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

1 (b) *COOPERATIVE ARRANGEMENTS*.—Section 503 of
2 the Controlled Substances Act (21 U.S.C. 873) is amend-
3 ed—

4 (1) *by striking subsection (c) and inserting the*
5 *following:*

6 “(c)(1) *The Attorney General shall, once every 6*
7 *months, prepare and make available to regulatory, licens-*
8 *ing, attorneys general, and law enforcement agencies of*
9 *States a standardized report containing descriptive and*
10 *analytic information on the actual distribution patterns,*
11 *as gathered through the Automated Reports and Consoli-*
12 *dated Orders System, or any subsequent automated system,*
13 *pursuant to section 307 and which includes detailed*
14 *amounts, outliers, and trends of distributor and pharmacy*
15 *registrants, in such States for the controlled substances con-*
16 *tained in schedule II, which, in the discretion of the Attor-*
17 *ney General, are determined to have the highest abuse.*

18 “(2) *If the Attorney General publishes the report de-*
19 *scribed in paragraph (1) once every 6 months as required*
20 *under paragraph (1), nothing in this subsection shall be*
21 *construed to bring an action in any court to challenge the*
22 *sufficiency of the information or to compel the Attorney*
23 *General to produce any documents or reports referred to*
24 *in this subsection.”.*

1 (c) *CIVIL AND CRIMINAL PENALTIES.*—Section 402 of
 2 the Controlled Substances Act (21 U.S.C. 842) is amend-
 3 ed—

4 (1) in subsection (a)—

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

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

9 (C) by inserting after paragraph (16) the
 10 following:

11 “(17) in the case of a registered manufacturer or
 12 distributor of opioids, to fail to review the most recent
 13 information, directly related to the customers of the
 14 manufacturer or distributor, made available by the
 15 Attorney General in accordance with section 307(f).”;
 16 and

17 (2) in subsection (c)—

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

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

23 “(ii) In the case of a violation described in clause (i)
 24 committed by a registered manufacturer or distributor of
 25 opioids and related to the reporting of suspicious orders for

1 *opioids, failing to maintain effective controls against diver-*
 2 *sion of opioids, or failing to review the most recent informa-*
 3 *tion made available by the Attorney General in accordance*
 4 *with section 307(f), the penalty shall not exceed \$100,000.”;*
 5 *and*

6 *(B) in paragraph (2)—*

7 *(i) in subparagraph (A), by inserting*
 8 *“or (D)” after “subparagraph (B)”;* and

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

10 *“(D) In the case of a violation described in subpara-*
 11 *graph (A) that was a violation of paragraph (5), (10), or*
 12 *(17) of subsection (a) committed by a registered manufac-*
 13 *turer or distributor of opioids that relates to the reporting*
 14 *of suspicious orders for opioids, failing to maintain effective*
 15 *controls against diversion of opioids, or failing to review*
 16 *the most recent information made available by the Attorney*
 17 *General in accordance with section 307(f), the criminal fine*
 18 *under title 18, United States Code, shall not exceed*
 19 *\$500,000.”.*

20 **SEC. 5. REPORT.**

21 *Not later than 1 year after the date of enactment of*
 22 *this Act, the Attorney General shall submit to Congress a*
 23 *report that provides information about how the Attorney*
 24 *General is using data in the Automation of Reports and*
 25 *Consolidated Orders System to identify and stop suspicious*

1 *activity, including whether the Attorney General is looking*
2 *at aggregate orders from individual pharmacies to multiple*
3 *distributors that in total are suspicious, even if no indi-*
4 *vidual order rises to the level of a suspicious order to a*
5 *given distributor.*

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