

115TH CONGRESS
2D SESSION

H. R. 6491

To amend the Controlled Substances Act to require the Drug Enforcement Administration to report certain information on distribution of opioids to manufacturers and distributors to help identify, report, and stop suspicious orders of opioids and reduce diversion rates, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 24, 2018

Ms. CASTOR of Florida (for herself and Mr. MCKINLEY) 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 amend the Controlled Substances Act to require the Drug Enforcement Administration to report certain information on distribution of opioids to manufacturers and distributors to help identify, report, and stop suspicious orders of opioids and reduce diversion rates, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Using Data to Prevent
3 Opioid Diversion Act of 2018”.

4 **SEC. 2. FINDINGS.**

5 Congress finds the following:

6 (1) In 2016, there were nearly 64,000 drug
7 overdose deaths in the United States. More than
8 42,000 of these deaths were opioid-related.

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

12 (A) provide effective controls against the
13 diversion of controlled substances;

14 (B) detect and disclose suspicious orders to
15 the Drug Enforcement Administration; and

16 (C) keep complete and accurate records re-
17 lating to the manufacture or distribution of
18 controlled substances.

19 (3) Despite the requirements described in para-
20 graph (2), it has been publicly reported that between
21 2006 and 2016, nearly 21,000,000 opioids were dis-
22 tributed to 2 pharmacies in Williamson, West Vir-
23 ginia, which has a population of approximately
24 3,000. It has been further reported that between
25 2007 and 2008, nearly 9,000,000 pills were distrib-

1 uted to a single pharmacy in Kermit, West Virginia,
2 which has a population of 392.

3 (4) Similarly, it has been publicly reported that
4 780,000,000 oxycodone and hydrocodone pills were
5 distributed to pharmacies throughout West Virginia
6 between 2007 and 2012. In the same period, more
7 than 1,700 people in the State died from overdoses
8 of these 2 substances.

9 (5) Drug manufacturers and distributors are
10 required to report the sale, delivery or other disposal
11 of narcotics to the Drug Enforcement Administra-
12 tion through the Automated Reports and Consoli-
13 dated Orders System.

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

23 (7) Although manufacturers and distributors
24 are already required to provide effective controls
25 against the diversion of controlled substances, this

1 lack of data sharing may create a barrier to better
2 identifying and stopping potentially suspicious or-
3 ders.

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

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

1 **SEC. 3. PROVISION AND REVIEW OF AUTOMATED REPORTS**
2 **AND CONSOLIDATED ORDERS SYSTEMS IN-**
3 **FORMATION.**

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

7 (1) by redesignating subsections (f), (g), and
8 (h) as subsections (g), (h), and (i), respectively; and

9 (2) by inserting after subsection (e) the fol-
10 lowing:

11 “(f)(1) The Attorney General shall, not less fre-
12 quently than quarterly, make the following information
13 available to manufacturers and distributors registered
14 under this title through the Automated Reports and Con-
15 solidated Orders System, or any subsequent automated
16 system developed by the Drug Enforcement Administra-
17 tion to monitor selected controlled substances:

18 “(A) The total number of distributors reg-
19 istered under this title that distribute controlled sub-
20 stances to a pharmacy or practitioner registered
21 under section 303(f), aggregated by the name and
22 address of each pharmacy and practitioner reg-
23 istrator.

24 “(B) The total quantity and type of opioids dis-
25 tributed, listed by Administration Controlled Sub-

1 stances Code Number, to each pharmacy and practi-
2 tioner registered under section 303(f).

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

7 “(3)(A) All manufacturers and distributors registered
8 under this title shall be responsible for reviewing the infor-
9 mation made available by the Attorney General under this
10 subsection.

11 “(B) In determining whether to initiate proceedings
12 under this title against a manufacturer or distributor reg-
13 istered under this title based on the failure of the reg-
14 istrant to maintain effective controls against diversion or
15 otherwise comply with the requirements of this title or the
16 regulations issued thereunder, the Attorney General may
17 take into account that the information made available
18 under this subsection was available to the registrant.

19 “(4) All of the reports required under this subsection
20 shall be provided in electronic format.”.

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

24 (1) by striking subsection (c) and inserting the
25 following:

1 “(c)(1) The Attorney General shall, once every 6
2 months, prepare and make available to regulatory, licens-
3 ing, attorneys general, and law enforcement agencies of
4 States a standardized report containing descriptive and
5 analytic information on the actual distribution patterns,
6 as gathered through the Automated Reports and Consoli-
7 dated Orders System, or any subsequent automated sys-
8 tem, pursuant to section 307. Such reports shall include
9 detailed amounts, outliers, and trends of distributor and
10 pharmacy registrants, in such States for the controlled
11 substances contained in schedule II, which, in the discre-
12 tion of the Attorney General, are determined to have the
13 highest abuse.

14 “(2) If the Attorney General publishes the report de-
15 scribed in paragraph (1) once every 6 months as required
16 under paragraph (1), nothing in this subsection shall be
17 construed to authorize an action to be brought in any
18 court to challenge the sufficiency of the information in the
19 report or to compel the Attorney General to produce any
20 reports referred to in this subsection.”.

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

24 (1) in subsection (a)—

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

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

5 (C) by inserting after paragraph (16) the
6 following:

7 “(17) in the case of a manufacturer or distribu-
8 tors of opioids registered under this title, to fail to
9 review the most recent information, directly related
10 to the customers of the manufacturer or distributor,
11 made available by the Attorney General in accord-
12 ance with section 307(f).”; and

13 (2) in subsection (c)—

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

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

19 “(ii) In the case of a violation described in clause (i)
20 committed by a manufacturer or distributor of opioids reg-
21 istered under this title and related to the reporting of sus-
22 picious orders for opioids, failing to maintain effective con-
23 trols against diversion of opioids, or failing to review the
24 most recent information made available by the Attorney

1 General in accordance with section 307(f), the penalty
2 shall not exceed \$100,000.”; and

3 (B) in paragraph (2)—

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

6 (ii) by adding at the end the fol-
7 lowing:

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

18 **SEC. 4. RULE OF CONSTRUCTION.**

19 Nothing in this Act should be construed to absolve
20 a drug manufacturer, drug distributor, or other Drug En-
21 forcement Administration registrant from the responsi-
22 bility of the manufacturer, distributor, or other registrant
23 to—

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

25 or

1 (2) maintain effective controls against diversion
2 in accordance with section 303 of the Controlled
3 Substances Act (21 U.S.C. 823) or any successor
4 law or associated regulation.

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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