II

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~**SECTION 1. SHORT TITLE.**~~

~~This Act may be cited as the "Using Data to Prevent Opioid Diversion Act of 2018".~~

SEC. 2. FINDINGS.

Congress finds the following:

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

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

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

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

(C) keep complete and accurate records relating to the manufacture or distribution of controlled substances.

(3) Despite the requirements described in paragraph (2), it has been publicly reported that between 2006 and 2016, nearly 21,000,000 opioids were distributed to 2 pharmacies in Williamson, West Virginia, which has a population of approximately 3,000. It has been further reported that between 2007 and 2008, nearly 9,000,000 pills were distributed to a single pharmacy in Kermit, West Virginia, which has a population of 392.

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

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

~~(5) Drug manufacturers and distributors are required to report the sale, delivery or other disposal of narcotics to the Drug Enforcement Administration through the Automated Reports and Consolidated Ordering System.~~

~~(6) Notwithstanding the reporting requirement described in paragraph (5), the Drug Enforcement Administration does not disclose the total quantity and type of opioids distributed to a single pharmacy or practitioner with those manufacturers and distributors who are required to input information into the Automated Reports and Consolidated Ordering System. This creates a barrier to identifying and stopping potentially suspicious orders.~~

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

(8) On an annual basis, the Attorney General of the United States is statutorily required to share the controlled substance or substances in schedule II that have the highest rates of abuse and to prepare and make available reports on the distribution patterns of such substances, with State regulatory, licensing, and law enforcement agencies. The Attorney General of the United States has entered into data sharing agreements with the attorneys general of the vast majority of States, Puerto Rico, and the District of Colombia to share, pursuant to State law and policy, data obtained from State prescription drug monitoring programs and other sources.

(9) To further reduce barriers associated with identifying suspicious patterns and stopping the diversion of opioids, the remaining States and territories of the United States should enter into similar agreements with, and to the greatest extent practical share data obtained from State prescription drug monitoring programs with, the Attorney General of the United States.

SEC. 3. PURPOSE.

(a) IN GENERAL.—The purpose of this Act is to provide drug manufacturers and distributors with access to anonymized information through the Automated Reports

and Consolidated Ordering System to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids and reduce diversion rates.

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

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

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

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

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

SEC. 4. AMENDMENTS.

(a) RECORDS AND REPORTS OF REGISTRANTS.—Section 307 of the Controlled Substances Act (21 U.S.C. 827) is amended—

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

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

''(f)(1) The Attorney General shall, not less frequently than quarterly, make the following information available to manufacturer and distributor registrants through the Automated Reports and Consolidated Ordering System, or any subsequent automated system developed by the Drug Enforcement Administration to monitor selected controlled substances:

''(A) The total number of distributor registrants that distribute controlled substances to a pharmacy or practitioner registrant, aggregated by the name and address of each pharmacy and practitioner registrant.

''(B) The total quantity and type of opioids distributed, listed by Administration Controlled Substances Code Number, to each pharmacy and practitioner registrant described in subparagraph (A).

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

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

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

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

(3) by inserting after subsection (i), as so redesignated, the following:

''(j) All of the reports required under this section shall be provided in an electronic format.''.

(b) COOPERATIVE ARRANGEMENTS.—Section 503 of the Controlled Substances Act (21 U.S.C. 873) is amended—

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

''(c)(1) The Attorney General shall, once every 6 months, prepare and make available to regulatory, licensing, attorneys general, and law enforcement agencies of States a standardized report containing descriptive and analytic information on the actual distribution patterns, as gathered through the Automated Reports and Consolidated Ordering System, or any subsequent automated system, pursuant to section 307 and which include detailed amounts, outliers, and trends of distributor and pharmacy registrants, in such States for the controlled substances

contained in schedule II, which, in the discretion of the Attorney General, are determined to have the highest abuse.

''(2) If the Attorney General publishes the report described in paragraph (1) once every 6 months as required under paragraph (1), nothing in this subsection shall be construed to bring an action in any court to challenge the sufficiency of the information or to compel the Attorney General to produce any documents or reports referred to in this subsection.''.

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

(1) in subsection (a)—

(A) in paragraph (15), by striking ''or'' at the end;

(B) in paragraph (16), by striking the period at the end and inserting ''; or''; and

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

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

each distribution of a controlled substance referred to in such information.''; and

(2) in subsection (c)—

(A) in paragraph (1), by striking subparagraph (B) and inserting the following:

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

''(ii) In the case of a violation described in clause (i) committed by a registered manufacturer or distributor of opioids and related to the reporting 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 penalty shall not exceed $100,000.''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ''or (D)'' after ''subparagraph (B)''; and

(ii) by adding at the end the following:

''(D) In the case of a violation described in subparagraph (A) that was a violation of paragraph (5), (10), or (17) of subsection (a) committed by a registered manufacturer or distributor of opioids that relates to the reporting

~~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.''.~~

~~SEC. 5. REPORT.~~

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Using Data to Prevent Opioid Diversion Act of 2018''.

SEC. 2. FINDINGS.

Congress finds the following:

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

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

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

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

(C) keep complete and accurate records relating to the manufacture or distribution of controlled substances.

(3) Despite the requirements described in paragraph (2), it has been publicly reported that between 2006 and 2016, nearly 21,000,000 opioids were distributed to 2 pharmacies in Williamson, West Virginia, which has a population of approximately 3,000. It has been further reported that between 2007 and 2008, nearly 9,000,000 pills were distributed to a single pharmacy in Kermit, West Virginia, which has a population of 392.

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

(5) Drug manufacturers and distributors are required to report the sale, delivery or other disposal of narcotics to the Drug Enforcement Administration through the Automated Reports and Consolidated Orders System.

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

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

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

law enforcement agencies. The Attorney General of the United States has entered into data sharing agreements with the attorneys general of the vast majority of States, Puerto Rico, and the District of Colombia to share, pursuant to State law and policy, data obtained from State prescription drug monitoring programs and other sources.

(9) To further reduce barriers associated with identifying suspicious patterns and stopping the diversion of opioids, the remaining States and territories of the United States should enter into similar agreements with, and to the greatest extent practical share data obtained from State prescription drug monitoring programs with, the Attorney General of the United States.

SEC. 3. PURPOSE.

(a) IN GENERAL.—The purpose of this Act is to provide drug manufacturers and distributors with access to anonymized information through the Automated Reports and Consolidated Orders System to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids and reduce diversion rates.

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

istrant from the responsibility of the manufacturer, distributor, or other registrant to—

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

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

SEC. 4. AMENDMENTS.

(a) RECORDS AND REPORTS OF REGISTRANTS.—Section 307 of the Controlled Substances Act (21 U.S.C. 827) is amended—

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

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

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

"(A) The total number of distributor registrants that distribute controlled substances to a pharmacy or

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

"(B) The total quantity and type of opioids distributed, listed by Administration Controlled Substances Code Number, to each pharmacy and practitioner registrant described in subparagraph (A).

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

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

"(B) In determining whether to initiate proceedings under this title against a registered manufacturer or distributor based on the failure of the registrant to maintain effective controls against diversion or otherwise comply with the requirements of this title or the regulations issued thereunder, the Attorney General may take into account that the information made available under this subsection was available to the registrant."; and

(3) by inserting after subsection (i), as so redesignated, the following:

"(j) All of the reports required under this section shall be provided in an electronic format.".

(b) COOPERATIVE ARRANGEMENTS.—Section 503 of the Controlled Substances Act (21 U.S.C. 873) is amended—

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

"(c)(1) The Attorney General shall, once every 6 months, prepare and make available to regulatory, licensing, attorneys general, and law enforcement agencies of States a standardized report containing descriptive and analytic information on the actual distribution patterns, as gathered through the Automated Reports and Consolidated Orders System, or any subsequent automated system, pursuant to section 307 and which includes detailed amounts, outliers, and trends of distributor and pharmacy registrants, in such States for the controlled substances contained in schedule II, which, in the discretion of the Attorney General, are determined to have the highest abuse.

"(2) If the Attorney General publishes the report described in paragraph (1) once every 6 months as required under paragraph (1), nothing in this subsection shall be construed to bring an action in any court to challenge the sufficiency of the information or to compel the Attorney General to produce any documents or reports referred to in this subsection.".

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(A) in paragraph (15), by striking "or" at the end;

(B) in paragraph (16), by striking the period at the end and inserting "; or"; and

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

"(17) in the case of a registered manufacturer or distributor of opioids, to fail to review the most recent information, directly related to the customers of the manufacturer or distributor, made available by the Attorney General in accordance with section 307(f).";

and

(2) in subsection (c)—

(A) in paragraph (1), by striking subparagraph (B) and inserting the following:

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

"(ii) In the case of a violation described in clause (i) committed by a registered manufacturer or distributor of opioids and related to the reporting 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 penalty shall not exceed $100,000.''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ''or (D)'' after ''subparagraph (B)''; and

(ii) by adding at the end the following:

''(D) In the case of a violation described in subparagraph (A) that was a violation of paragraph (5), (10), or (17) of subsection (a) committed by a registered manufacturer or distributor of opioids that relates to the reporting 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.''.

SEC. 5. REPORT.

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

activity, including whether the Attorney General is looking at aggregate orders from individual pharmacies to multiple distributors that in total are suspicious, even if no individual order rises to the level of a suspicious order to a given distributor.

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