

116TH CONGRESS
1ST SESSION

S. 2686

To improve reporting of the distribution of controlled substances, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 23, 2019

Mr. GARDNER (for himself and Mr. COONS) introduced the following bill;
which was read twice and referred to the Committee on the Judiciary

A BILL

To improve reporting of the distribution of controlled substances, 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 “Suspicious Order Iden-
5 tification Act of 2019”.

6 **SEC. 2. STRENGTHENING ARCOS.**

7 Section 307(d) of the Controlled Substances Act (21
8 U.S.C. 827(d)) is amended to read as follows:

9 “(1)(A) Every registrant under section 303 shall and
10 in such form as the Attorney General may require, make

1 reports in electronic format to the Attorney General of
 2 every sale, delivery, or other disposal (other than by dis-
 3 pensing by a practitioner) by the registrant of any con-
 4 trolled substance, identifying by the registration number
 5 assigned under this title the person or establishment (un-
 6 less exempt from registration under section 302(d)) to
 7 whom such sale, delivery, or other disposal was made.

8 “(B) Every registrant shall make each report re-
 9 quired under subparagraph (A)—

10 “(i) not later than 30 days after the sale, deliv-
 11 ery, or other disposal; or

12 “(ii) after the date on which the real-time re-
 13 porting system is established under section 3(e)(3)
 14 of the Suspicious Order Identification Act of 2019
 15 is implemented, in real time.”.

16 **SEC. 3. SUSPICIOUS ORDERS TASK FORCE.**

17 (a) DEFINITIONS.—In this section:

18 (1) ADMINISTRATOR.—The term “Adminis-
 19 trator” means the Administrator of the Drug En-
 20 forcement Administration.

21 (2) CONTROLLED SUBSTANCE; DISTRIBUTOR;
 22 MANUFACTURER.—The terms “controlled sub-
 23 stance”, “distributor”, and “manufacturer” have the
 24 meanings given those terms in section 102 of the
 25 Controlled Substances Act (21 U.S.C. 802).

1 (3) REAL TIME.—The term “real time” means
2 with as little delay as technically and economically
3 feasible, as determined by the Attorney General fol-
4 lowing the program designed under subsection
5 (e)(1), but not to exceed 24 hours.

6 (4) REGISTRANT.—The term “registrant”—
7 (A) means a person registered under sec-
8 tion 303 of the Controlled Substances Act (21
9 U.S.C. 823); and

10 (B) does not include a practitioner.

11 (b) ESTABLISHMENT.—The Attorney General, in
12 consultation with the Director of the Office of National
13 Drug Control Policy and the Secretary of Health and
14 Human Services, shall establish a Suspicious Order Moni-
15 toring Task Force (referred to in this section as the “Task
16 Force”).

17 (c) COMPOSITION.—

18 (1) IN GENERAL.—The Task Force shall be
19 composed of appropriate personnel from—

20 (A) the Department of Justice;

21 (B) the Drug Enforcement Administration;

22 (C) the Office of National Drug Control
23 Policy;

24 (D) the National Institute of Standards
25 and Technology; and

(E) other appropriate Federal, State, and local law enforcement and regulatory agencies with experience in investigating and prosecuting illegal transactions of controlled substances as determined by the Attorney General, in consultation with the Secretary of Health and Human Services.

(2) CONSULTANTS.—The Task Force shall consult with—

(A) industry members, including—

(i) data analytic professionals;

(ii) community pharmacies that dispense controlled substances;

(iii) chain pharmacies that dispense controlled substances;

(iv) distributors of controlled substances;

(v) manufacturers of controlled substances;

(vi) State and local public health officials; and

(vii) other relevant industry professionals; and

(B) relevant industry regulators and entities that utilize real-time reporting of trans-

1 actions, orders, or other activities with the goal
2 of identifying suspicious activity, such as appro-
3 priate personnel from the Financial Crimes En-
4 forcement Network and money transfer indus-
5 try professionals.

6 (d) MEETINGS.—

7 (1) IN GENERAL.—The Task Force shall meet
8 not less frequently than 4 times per year and at
9 such other times as may be determined necessary by
10 the Task Force.

11 (2) INITIAL MEETING.—Not later than 60 days
12 after the date of enactment of this Act, the Task
13 Force shall hold the initial meeting of the Task
14 Force.

15 (e) PRELIMINARY ORDER EVALUATION PROGRAM.—

16 (1) IN GENERAL.—

17 (A) DESIGN.—Not later than 60 days after
18 the date on which the Task Force holds the ini-
19 tial meeting required under subsection (d)(2),
20 the Task Force shall begin to design a program
21 in accordance with paragraph (2).

22 (B) PURPOSE.—The program described in
23 subparagraph (A) shall be designed to share
24 necessary data, in a limited capacity, with reg-
25 istrants in order to provide registrants with in-

1 formation to identify suspicious ordering in real
2 time.

3 (C) DEADLINE FOR COMPLETION.—Not
4 later than 8 months after the date of enactment
5 of this Act, the Task Force shall complete the
6 design required under subparagraph (A).

7 (2) REQUIREMENTS.—

8 (A) IN GENERAL.—The program required
9 under paragraph (1) shall establish a process
10 for—

11 (i) transitioning to a requirement to
12 report in real time to the Attorney General
13 under section 307(d) of the Controlled
14 Substances Act (21 U.S.C. 827(d)) every
15 sale, delivery, or other disposal by a reg-
16 istrant of any controlled substance;

17 (ii) limited sharing in real time of Au-
18 tomation of Reports and Consolidated Or-
19 ders System (commonly known as
20 “ARCOS”) data with registrants to share
21 necessary data, in a limited capacity, with
22 registrants in order to provide registrants
23 with information to identify suspicious or-
24 dering in real time; and

1 (iii) ensuring data privacy, data de-
2 identification, protection of trade secrets
3 and purchasing history.

4 (B) OTHER CONSIDERATIONS.—In design-
5 ing the program under paragraph (1), the Task
6 Force shall take into consideration—

7 (i) the inclusion of a waiver process
8 for pharmacies and other registrants un-
9 able to transmit orders electronically on
10 the date of enactment of this Act;

11 (ii) a mechanism to ensure that the
12 costs of running the program are not
13 passed through to customers of registrants,
14 unless the registrants are customer of
15 other registrants;

16 (iii) technical requirements for ensur-
17 ing that registrants may access all relevant
18 de-identified data, with output provided in
19 a standard database file format; and

20 (iv) a mechanism to ensure that the
21 program required to be designed under
22 subparagraph (A) is updated based on
23 feedback from industry members and other
24 relevant entities.

1 (3) IMPLEMENTATION.—Not later than 1 year
2 after the date of enactment of this Act, the Attorney
3 General shall—

4 (A) implement the program designed under
5 paragraph (1) to collect and share in real time
6 data for registrants to evaluate the orders of
7 controlled substances from distributors to man-
8 ufacturers and from pharmacies to distributors;
9 or

10 (B) otherwise implement a program to col-
11 lect and share in real time data for drug manu-
12 facturers and distributors, by providing access
13 to anonymized information to help drug manu-
14 facturers and distributors identify, report, and
15 stop suspicious orders of controlled substances
16 and reduce diversion rates.

17 (4) RECOMMENDED STATUTORY AND REGU-
18 LATORY CHANGES.—In designing the program re-
19 quired under paragraph (1), the Task Force—

20 (A) shall submit to the Attorney General
21 any recommendations for necessary amend-
22 ments to regulations of the Department of Jus-
23 tice relating to the requirements for ordering
24 schedule II controlled substances, so as to allow
25 uniform electronic ordering of controlled sub-

stances in schedules II, III, IV, and V electronically through the program; and

(B) may submit to Congress any recommendations for necessary legislative changes so that a real-time data analytics solution can be used across the United States.

(5) RESPONSIBILITY OF REGISTRANTS.—All registered drug manufacturers and distributors shall be responsible for reviewing any information made available by the Attorney General and complying with any regulations regarding the program designed under paragraph (1) and implemented under paragraph (3).

(f) FUNDING.—

(1) IN GENERAL.—The Attorney General, acting through the Administrator, shall use amounts collected as fees for distributors and registrants under section 303 of the Controlled Substances Act (21 U.S.C. 823) and section 1007 of the Controlled Substances Import and Export Act (21 U.S.C. 957) to carry out this section.

(2) OFFSET.—

(A) IN GENERAL.—The Administrator may, on an equal basis and in accordance with subparagraph (B), increase the fees described

1 in paragraph (1) for distributors and reg-
2 istrants to the extent necessary to defray the
3 costs of this section.

4 (B) TIERED FEE.—The Administrator
5 shall establish a tiered user fee for distributors
6 and registrants in proportion to the volume of
7 sales and purchases.

8 (g) APPLICABILITY OF FACCA.—

9 (1) IN GENERAL.—Except as provided in para-
10 graph (2), the Federal Advisory Committee Act (5
11 U.S.C. App.) shall apply to the Task Force.

12 (2) TERMINATION.—The Task Force shall ter-
13 minate on the date on which the program is fully
14 implemented under subsection (e)(3).

15 (h) RULES OF CONSTRUCTION.—Nothing in this Act
16 shall be construed as relieving any manufacturer, dis-
17 tributor, or other registrant from the responsibilities of
18 the manufacturer, distributor, or other registrant, as the
19 case may be, to—

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

21 (2) maintain effective controls against diversion
22 in accordance with section 303 of the Controlled
23 Substances Act (21 U.S.C. 823); and

24 (3) comply with the requirements established in
25 section 1301.74(b) of title 21, Code of Federal Reg-

- 1 ulations, or any successor regulation thereto, with
- 2 respect to suspicious orders.

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