

116TH CONGRESS
1ST SESSION

H. R. 4814

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 23, 2019

Ms. MATSUI (for herself and Mr. JOHNSON of Ohio) 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 subse-
quently determined by the Speaker, in each case for consideration of such
provisions as fall within the jurisdiction of the committee concerned

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:

1 “(1)(A) Every registrant under section 303 shall and
 2 in such form as the Attorney General may require, make
 3 reports in electronic format to the Attorney General of
 4 every sale, delivery, or other disposal (other than by dis-
 5 pensing by a practitioner) by the registrant of any con-
 6 trolled substance, identifying by the registration number
 7 assigned under this title the person or establishment (un-
 8 less exempt from registration under section 302(d)) to
 9 whom such sale, delivery, or other disposal was made.

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

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

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

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

19 (a) DEFINITIONS.—In this section:

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

23 (2) CONTROLLED SUBSTANCE; DISTRIBUTOR;
 24 MANUFACTURER.—The terms “controlled sub-
 25 stance”, “distributor”, and “manufacturer” have the

1 meanings given those terms in section 102 of the
2 Controlled Substances Act (21 U.S.C. 802).

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

8 (4) REGISTRANT.—The term “registrant”—

9 (A) means a person registered under sec-
10 tion 303 of the Controlled Substances Act (21
11 U.S.C. 823); and

12 (B) does not include practitioner.

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

19 (c) COMPOSITION.—

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

22 (A) the Department of Justice;

23 (B) the Drug Enforcement Administration;

24 (C) the Office of National Drug Control
25 Policy;

1 (D) the National Institute of Standards
2 and Technology; and

3 (E) other appropriate Federal, State, and
4 local law enforcement and regulatory agencies
5 with experience in investigating and prosecuting
6 illegal transactions of controlled substances as
7 determined by the Attorney General, in con-
8 sultation with the Secretary of Health and
9 Human Services.

10 (2) CONSULTANTS.—The Task Force shall con-
11 sult with—

12 (A) industry members, including—

13 (i) data analytic professionals;

14 (ii) community pharmacies that dis-
15 pense controlled substances;

16 (iii) chain pharmacies that dispense
17 controlled substances;

18 (iv) distributors of controlled sub-
19 stances;

20 (v) manufacturers of controlled sub-
21 stances;

22 (vi) State and local public health offi-
23 cials; and

24 (vii) other relevant industry profes-
25 sionals; and

1 (B) relevant industry regulators and enti-
2 ties that utilize real-time reporting of trans-
3 actions, orders, or other activities with the goal
4 of identifying suspicious activity, such as appro-
5 priate personnel from the Financial Crimes En-
6 forcement Network and money transfer indus-
7 try professionals.

8 (d) MEETINGS.—

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

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

17 (e) PRELIMINARY ORDER EVALUATION PROGRAM.—

18 (1) IN GENERAL.—

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

24 (B) PURPOSE.—The program described in
25 subparagraph (A) shall be designed to share

1 necessary data, in a limited capacity, with reg-
2 istrants in order to provide registrants with in-
3 formation to identify suspicious ordering in real
4 time.

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

9 (2) REQUIREMENTS.—

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

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

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

1 with information to identify suspicious or-
2 dering in real time; and

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

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

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

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

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

22 (iv) a mechanism to ensure that the
23 program required to be designed under
24 subparagraph (A) is updated based on

1 feedback from industry members and other
2 relevant entities.

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

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

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

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

22 (A) shall submit to the Attorney General
23 any recommendations for necessary amend-
24 ments to regulations of the Department of Jus-
25 tice relating to the requirements for ordering

1 schedule II controlled substances, so as to allow
2 uniform electronic ordering of controlled sub-
3 stances in schedules II, III, IV, and V electroni-
4 cally through the program; and

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

9 (5) RESPONSIBILITY OF REGISTRANTS.—All
10 registered drug manufacturers and distributors shall
11 be responsible for reviewing any information made
12 available by the Attorney General and complying
13 with any regulations regarding the program designed
14 under paragraph (1) and implemented under para-
15 graph (3).

16 (f) FUNDING.—

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

24 (2) OFFSET.—

1 (A) IN GENERAL.—The Administrator
2 may, on an equal basis and in accordance with
3 subparagraph (B), increase the fees described
4 in paragraph (1) for distributors and reg-
5 istrants to the extent necessary to defray the
6 costs of this section.

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

11 (g) APPLICABILITY OF FACA.—

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

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

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

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

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

4 (3) comply with the requirements established in
5 section 1301.74(b) of title 21, Code of Federal Reg-
6 ulations, or any successor regulation thereto, with
7 respect to suspicious orders.

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